IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of:

Inventors:	Harder et al.
Serial No.:	10/706,717
Filed:	November 11, 2003
For:	ENDOPROSTHESIS
Art Unit:	3773
Examiner:	Melanie Ruano Tyson

BRIEF ON APPEAL

To: Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

To the Commissioner:

This is an appeal under 37 C.F.R. §1.191 to the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office from the final rejection of claims 1-20 in the above-identified patent application. One (1) copy of Appellant's Brief on Appeal is filed herewith, and the requisite filing fee under 37 C.F.R. §1.17(f) is also paid herewith.

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X. Related Proceedings Appendix

I. REAL PARTY IN INTEREST

The real party in interest in the present application is Biotronik AG, by assignment from Biotronik GmbH & Co. KG, recorded in the United States Patent and Trademark Office at Reel 015018, Frame 0625. Biotronik GmbH & Co. KG obtained its rights in the application by assignment from inventors Claus Harder, Bodo Gerold, Heinz Mueller, and Bernd Heublein. The assignment from the inventors to Biotronik GmbH & Co. KG is recorded in the United States Patent and Trademark Office at Reel 014702, Frame 0746.

II. RELATED APPEALS AND INTERFERENCES

There have been no previous appeals in this application.

There have been no interferences or related litigation.

III. STATUS OF CLAIMS

The status of the claims in this application is:

1. TOTAL NUMBER OF CLAIMS IN APPLICATION

There are 37 pending claims in this application, numbered 1-37.

In the Office Action of February 7, 2008, the Examiner issued a final office action rejecting pending claims 1–17 and 19-35 under 35 U.S.C. § 103(a) as being obvious over U.S. Pat. No. 6,979,347 to Wu and claims 18 and 36–37 under 35 U.S.C. § 103(a) as being obvious over U.S. Pat. No. 6,979,347 to Wu in view of U.S. Patent No. 6,676,697 to Richter.

2. STATUS OF ALL OF THE CLAIMS

A. Claims canceled: NONE.

B. Claims withdrawn from consideration but not canceled: NONE.

C. Claims pending: Claims 1-37.

D. Claims allowed: NONE.

E. Claims rejected: 1-37.

3. CLAIMS ON APPEAL

The claims on appeal are claims 1-37.

IV. STATUS OF AMENDMENTS

No Amendments have been filed subsequent to the Final Action of February 7, 2008.

V. SUMMARY OF CLAIMED SUBJECT MATTER

All citations to the specification refer to the specification that was filed on November 11, 2003.

Claim 1, the sole independent claim under consideration, is directed to an endoprosthesis (Paragraph 0008, page 2, line 28) comprising a carrier structure comprising a metallic material wherein the metallic material comprises a magnesium alloy of the following composition (Paragraph 0008, page 2, lines 29-30):

Magnesium:	>90% (Paragraph 0008, page 2, line 31)
Yttrium:	3.7% - 5.5% (Paragraph 0008, page 2, line 32)
Rare earths:	1.5% - 4.4% (Paragraph 0008, page 2, line 33) and
Balance:	<1% (Paragraph 0008, page 2, line 34).

Claims 18, 36 and 37 each recite an endoprosthesis, wherein a first plurality of the plurality of legs (Paragraph 0015, page 4, lines 20-21) form leg rings (Paragraph 0017, page 4, lines 29-30) and a second plurality of the plurality of legs define connecting legs that connect adjacent leg rings together (Paragraph 0017, page 4, line 30), wherein the connecting legs are of a smaller cross-sectional area or a smaller minimum diameter than the legs which form the leg rings (Paragraph 0017, page 4, lines 30-32).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claims 1–17 and 19-35 are unpatentable under 35 U.S.C. § 103(a) as being obvious over U.S. Pat. No. 6,979,347 to Wu.
2. Whether claims 18 and 36–37 are unpatentable under 35 U.S.C. § 103(a) as being obvious over U.S. Pat. No. 6,979,347 to Wu in view of U.S. Patent No. 6,676,697 to Richter.

VII. ARGUMENTS

1. The Rejection of Record

Currently, claims 1 - 37 are pending and under consideration in the present application. Claims 1-37 stand rejected.

In the Office Action of February 7, 2008, The Examiner rejected claims 1–17 and 19-35 under 35 U.S.C. § 103(a) as being obvious over U.S. Pat. No. 6,979,347 to Wu (hereinafter "Wu"). Claims 18 and 36–37 were rejected under 35 U.S.C. § 103(a) as being obvious over Wu in view of U.S. Patent No. 6,676,697 to Richter (hereinafter "Richter").

A. Rejection of Claims 1-17 and 19-35

The Examiner maintains that Wu discloses an endoprosthesis having a carrier structure that comprises a magnesium alloy. The Examiner further maintains that it would have been obvious to a person of ordinary skill in the art to use a magnesium alloy of the composition claimed in such an endoprosthesis at the time of the invention because such alloys are well known. In support of this contention, the Examiner cites U.S. Pat. No 4,401,621 to Unsworth as disclosing an alloy of such a composition and having good tensile properties. It should be noted that the Examiner cites Unsworth as showing that magnesium alloys of this composition but without officially relying on Unsworth in combination with Wu.

B. Rejection of Claims 18 and 36-37

The Examiner further maintains that Richter provides a stent having a plurality of members and connectors, and teaches that reducing the width of the connectors provides improved flexibility. The Examiner concludes that it would have been obvious, at the time of the invention, to one of ordinary skill in the art, to construct the connecting legs of Wu's device with

a smaller cross-sectional area as taught by Richter to arrive at the claimed invention as recited in claims 18 and 36-37.

2. Claims Rejections under 35 U.S.C. §103(a)

A claimed invention is unpatentable under 35 U.S.C. §103 if the differences between it and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. 35 U.S.C. § 103 (1994); *Graham v. John Deere Co.,* 383 U.S. 1, 14 (1966); *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___ , No. 04-1350, *slip op.* at 2 (2007). The ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries, including (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. *Graham*, 383 U.S. at 17-18; *KSR Int'l* at 2.

To reach a proper determination under §103, the Examiner must step backward in time and into the shoes of the hypothetical person of ordinary skill in the art when the invention was unknown and just before it was made. MPEP §2142. The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art. MPEP §2142.

To establish obviousness, there must be some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in

the art, to modify the reference or to combine reference teachings. (MPEP § 2143.) "There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." *In re Rouffet,* 149 F.3d 1350, 1357, 47 U.S.P.Q.2d 1453, 1457-58 (Fed. Cir. 1998).

Recently, the Supreme Court rejected the previous use of the "teaching, suggestion, or motivation" (TSM) test as a "rigid and mandatory (formula)" that "limits the obviousness inquiry." *KSR Int'l Co.,* slip opinion at 15. Instead, the Supreme Court ruled that the TSM test should be used as a "general principle" and to provide a "helpful insight." *KSR Int'l Co.,* slip opinion at 15. However, the Supreme Court also reiterated, that an invention is not shown to be obvious "merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR Int'l Co.* at 14. Furthermore, the Supreme Court did not eliminate the motivation to combine from an obviousness analysis. To the contrary, the Court indicated, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed invention does." *KSR Int'l Co.* at 15. Therefore, while the Supreme Court's decision in *KSR Int'l* expands the possible sources of motivation to combine, it does not eliminate the requirement that there be a motivation to combine.

Ultimately, the "motivation to combine" criterion provides "the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis." *Dembiczak*, 175 F.3d at 999, 50 U.S.P.Q.2d at 1617. This is because "most if not all inventions arise from a combination of old elements," potentially allowing every element of the claimed invention to be

found in the prior art. *In re Kotzab*, 217 F.3d 1365, 1369-70, 55 U.S.P.Q.2d 1313, 1316 (Fed. Cir. 2000). Solely identifying each element of the claimed invention in the prior art is not enough to defeat patentability of the invention as a whole, unless there existed a teaching, suggestion, or motivation to combine the prior art references. *Kotzab*, 217 F.3d at 1370, 55 U.S.P.Q.2d at 1316-17. Otherwise, "rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention." *Rouffet,* 149 F.3d at 1357, 47 U.S.P.Q.2d at 1457. Thus, the initial burden is on the examiner to establish the existence of a teaching, suggestion, or motivation to combine the prior art references at the time the invention was made.

A. Rejection of Claims 1-17 and 19-35

i. Determination Of The Scope And Contents Of The Prior Art

As stated above, the Examiner maintains that Wu discloses an endoprosthesis having a carrier structure that comprises a magnesium alloy and that it would have been obvious to a person of ordinary skill in the art to use a magnesium alloy of the composition claimed in such an endoprosthesis at the time of the invention because such alloys are well known. The Examiner cites U.S. Pat. No 4,401,621 to Unsworth as disclosing an alloy of such a composition and having good tensile properties.

As stated previously, although Wu does generally disclose the option of using a magnesium-based alloy in a stent, Wu also makes no mention of the use of any specific magnesium alloy. Wu merely mentions magnesium once in passing among a list of potential

components, "Arm elements 22 and connecting elements 24 are typically fabricated from a metallic material or an alloy, such as stainless steel (e.g., 316L), MP35N, MP20N, tantalum, nickel-titanium alloy (commercially available as Nitinol™), platinum-iridium alloy, gold, magnesium, or combinations of alloys." (Column 4, lines 30-35). This disclosure of magnesium alloys in general, which includes a virtually limitless number of alloys, provides no teaching or suggestion of any specific alloy composition, including the compositions encompassed by the claims.

The Examiner apparently recognizes the insufficiency of the disclosure of Wu in establishing the alleged obviousness of the claims and therefore cites Unsworth as providing a specific magnesium alloy, which allegedly renders the present invention obvious. However, Unsworth provides no teaching or suggestion that such alloys are useful in stents or endoprostheses. Instead, Unsworth provides that these alloys are useful in aerospace applications (col. 1, lines 6-12). Unsworth only tests the properties of the disclosed alloy at temperatures of 200°C and above, which are far outside the range of physiological temperature, 37°C.

ii. Level Of Ordinary Skill In The Art

The Examiner has not explicitly provided a statement regarding the level of ordinary skill in the art. The Applicants maintain that a person having ordinary skill in the art to which the invention pertains, biomedical device design and engineering, would hold an undergraduate degree in Biology, Biomedical Engineering or a similar, closely related area.

iii. Differences Between The Claimed Invention And The Prior Art

The differences between the claimed invention and the prior art make the claimed invention nonobvious over Wu, either alone or in combination with Unsworth. As noted above, Wu merely provides a general disclosure of the use of magnesium alloys in a stent. Wu also provides no teaching or suggestion of the use of a composition containing yttrium in an endoprosthesis. Claim 1, however, provides a specific magnesium alloy, namely one having more than 90% magnesium, 3.7% - 5.5% yttrium, 1.5% - 4.4% rare earths, and a balance of less than 1%. Neither Wu nor Unsworth teach or suggest that the claimed magnesium alloy composition would have any properties necessary to be suitable for use in an endoprosthesis.

First, as stated previously, such a material must be biocompatible generally. The Examiner provides no teaching or suggestion, either in the cited prior art or in the knowledge generally available to one of ordinary skill in the art, that a magnesium alloy containing yttrium is compatible with use in an endoprosthesis. Additionally, while Unsworth indicates that a magnesium alloy provides good tensile properties, there is no indication, either in Wu or Unsworth or in the general knowledge of a person having ordinary skill in the art, that such an alloy would have other properties also required in an endoprothesis such as torsional strength, minimization of re-stenosis, or minimization of inflamation.

In response to the Applicants' argument that neither Wu nor Unsworth teach or suggest that such an alloy would provide advantageous properties such as prevention of restenosis from sustained tissue growth prevention, a lack of inflammatory effect, and decomposition products

which not only have no negative effect, but can actually have a positive effect, the Examiner maintains that a result that would flow logically from the teaching of the prior art is not patentable. However, the Examiner provides no indication of how one of skill in the art would consider a magnesium alloy as allegedly generally known in the art, or as specifically used in aerospace applications as taught by Unsworth, to "logically flow" to use in an endoprosthesis, particularly without any teaching regarding the properties mentioned above or any other advantageous properties. The Examiner only makes a bald assertion to this effect. Neither Wu nor Unsworth offer such advantages or provide any desirability for the use of such an alloy in an endoprosthesis as claimed.

A person having ordinary skill in the art, after reviewing the contents of both Wu and Unsworth as a whole, would not have been motivated to modify Wu or to combine Wu and Unsworth, to arrive at the present invention. Under *KSR*, an invention is not shown to be obvious "merely by demonstrating that each of its elements was, independently, known in the prior art," *KSR Int'l Co.* at 14. A person of ordinary skill in the art, noting the differences between the cited prior art and the claimed invention discussed above, would not have considered this to be a simple combination of known elements resulting in a predictable result as alleged by the Examiner. Therefore, the claimed invention would not have been obvious to one of ordinary skill in the art at the time of the invention.

B. Rejection of Claims 18 and 36-37

i. Determination Of The Scope And Contents Of The Prior Art

As stated above, Wu generally provides the option of using a magnesium-based alloy in a stent, but does not mention any specific magnesium alloy. Wu only mentions magnesium among a list of potential components. This disclosure of magnesium alloys in general includes a virtually limitless number of alloys and Wu provides no teaching or suggestion of any specific alloy composition, including the compositions encompassed by the claims.

Richter provides "a stent having a plurality of members and connectors" in which "reducing the width of the connectors provides a device with greater flexibility." (Office Action of Feb 7, 2008, page 3, lines 20-22). Richter provides no teaching or suggestion of the use of a magnesium alloy in an endoprosthesis.

ii. Level Of Ordinary Skill In The Art

As stated above, the Examiner has not explicitly provided a statement regarding the level of ordinary skill in the art. The Applicants maintain that a person having ordinary skill in the art to which the invention pertains, biomedical device design and engineering, would hold an undergraduate degree in Biology, Biomedical Engineering or a similar, closely related area.

iii. Differences Between The Claimed Invention And The Prior Art

As stated above, Wu does not mention the use of any specific magnesium alloy in a stent but only generally provides the option of using a magnesium-based alloy. For example, the Examiner provides no teaching or suggestion, either in the cited prior art or in the knowledge

generally available to one of ordinary skill in the art, that a yttrium-containing alloy would be compatible with use in an endoprosthesis. Additionally, there is no indication, either in Wu or in the general knowledge of a person having ordinary skill in the art, a magnesium alloy as recited in the claims would have other properties also required in an endoprothesis.

Likewise, Richter provides no teaching or suggestion of the use of a magnesium alloy in an endoprosthesis. The Examiner only relies on Richter for the teaching of "a stent having a plurality of members and connectors" in which reducing the width of the connectors provides a device with greater flexibility." (Office Action of Feb 7, 2008, page 3, lines 20-22).

C. Conclusion

The Applicants respectfully assert that all of pending claims 1-37 are allowable for at least the following reasons:

One of ordinary skill in the art would not have found any suggestion to modify Wu or to combine Wu with Unsworth or Richter to use a magnesium alloy as disclosed by Unsworth as an a magnesium alloy in a stent of Wu. One of ordinary skill in the art would have had no reasonable expectation of success in combining the teachings of the references as suggested by the Examiner. Such a suggestion to combine the references or expectation of success in making the combination can only be the result of impermissible hindsight.

In accordance with the foregoing, the Applicants respectfully request reversal of the Examiner's decision rejecting the claims and allowance of all claims. This Appeal Brief is due

with a one month extension of time if filed on or before September 2, 2008, as this date is the next business day after September 1, 2008, which fell on a federal holiday.

Respectfully submitted,

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VIII. APPENDIX OF CLAIMS INVOLVED IN THE APPEAL

1. (Rejected) An endoprosthesis, comprising:

a carrier structure comprising a metallic material;

wherein the metallic material comprises a magnesium alloy of the following composition:

Magnesium:	>90%
Yttrium:	3.7% - 5.5%
Rare earths:	1.5% - 4.4% and
Balance:	<1%.

2. (Rejected) The endoprosthesis of claim 1, wherein:

the yttrium proportion in the magnesium alloy is between 4% and 5%.

3. (Rejected) The endoprosthesis of claim 1, wherein:

the rare earths proportion in the magnesium alloy is between 1.5% and 4%.

4. (Rejected) The endoprosthesis of claim 1, wherein:

the rare earths proportion in the magnesium alloy comprises neodymium.

5. (Rejected) The endoprosthesis of claim 1, wherein:

the balance proportion in the magnesium alloy is formed for the major part by zirconium.

6. (Rejected) The endoprosthesis of claim 1, wherein:

the carrier structure consists essentially of the magnesium alloy.

7. (Rejected) The endoprosthesis of claim 1, wherein:

the carrier structure provides a cell survival rate of over about 70 percent upon cultivation of smooth muscle cells with the eluate of the material of the carrier structure

in comparison with untreated cells, or a proliferation inhibition effect below about 20 percent with respect to untreated smooth muscle cells.

8. (Rejected) The endoprosthesis of claim 1, wherein:

the endoprosthesis is in the form of an intraluminal endoprosthesis.

9. (Rejected) The endoprosthesis of claim 8, wherein:

the endoprosthesis is in the form of a stent.

10. (Rejected) The endoprosthesis of claim 9, wherein:

the endoprosthesis is in the form of a coronary stent.

11. (Rejected) The endoprosthesis of claim 9, wherein:

the endoprosthesis is in the form of a self-expanding stent.

12. (Rejected) The endoprosthesis of claim 1, wherein:

the carrier structure is produced by cutting a tube from one piece.

13. (Rejected) The endoprosthesis of claim 1, wherein:

the carrier structure is formed from a wire which contains the magnesium alloy.

14. (Rejected) The endoprosthesis of claim 1, wherein:

the carrier structure encloses an elongated hollow space which is open at its ends.

15. (Rejected) The endoprosthesis of claim 14, wherein:

the carrier structure is of a lattice-like structure and is formed by a plurality of legs and radial openings enclosed by said plurality of legs.

16. (Rejected) The endoprosthesis of claim 15, wherein:

the plurality of legs all have a similar cross-sectional area such that a ratio of largest to smallest cross-sectional area is smaller than 2.

17. (Rejected) The endoprosthesis of claim 15, wherein:

the plurality of legs all have a similar minimum diameter such that a ratio of largest to smallest minimum diameter is less than 2.

18. (Rejected) The endoprosthesis of claim 15, wherein:

a first plurality of the plurality of legs form leg rings and a second plurality of the plurality of legs define connecting legs that connect adjacent leg rings together,

wherein the connecting legs are of a smaller cross-sectional area or a smaller minimum diameter than the legs which form the leg rings.

19. (Rejected) The endoprosthesis of claim 1, wherein:

the endoprosthesis carries a physiologically effective active substance.

20. (Rejected) The endoprosthesis of claim 19, wherein:

the endoprosthesis is coated with at least one drug.

21. (Rejected) The endoprosthesis of claim 2, wherein:

the carrier structure consists essentially of the magnesium alloy.

22. (Rejected) The endoprosthesis of claim 3, wherein:

the carrier structure consists essentially of the magnesium alloy.

23. (Rejected) The endoprosthesis of claim 4, wherein:

the carrier structure consists essentially of the magnesium alloy.

24. (Rejected) The endoprosthesis of claim 5, wherein:

the carrier structure consists essentially of the magnesium alloy.

25. (Rejected) The endoprosthesis of claim 2, wherein:

the carrier structure provides a cell survival rate of over about 70 percent upon cultivation of smooth muscle cells with the eluate of the material of the carrier structure in comparison with untreated cells, or a proliferation inhibition effect below about 20 percent with respect to untreated smooth muscle cells.

26. (Rejected) The endoprosthesis of claim 3, wherein:

the carrier structure provides a cell survival rate of over about 70 percent upon cultivation of smooth muscle cells with the eluate of the material of the carrier structure in comparison with untreated cells, or a proliferation inhibition effect below about 20 percent with respect to untreated smooth muscle cells.

27. (Rejected) The endoprosthesis of claim 4, wherein:

the carrier structure provides a cell survival rate of over about 70 percent upon cultivation of smooth muscle cells with the eluate of the material of the carrier structure in comparison with untreated cells, or a proliferation inhibition effect below about 20 percent with respect to untreated smooth muscle cells.

28. (Rejected) The endoprosthesis of claim 5, wherein:

the carrier structure provides a cell survival rate of over about 70 percent upon cultivation of smooth muscle cells with the eluate of the material of the carrier structure in comparison with untreated cells, or a proliferation inhibition effect below about 20 percent with respect to untreated smooth muscle cells.

29. (Rejected) The endoprosthesis of claim 6, wherein:

the carrier structure provides a cell survival rate of over about 70 percent upon cultivation of smooth muscle cells with the eluate of the material of the carrier structure in comparison with untreated cells, or a proliferation inhibition effect below about 20 percent with respect to untreated smooth muscle cells.

30. (Rejected) The endoprosthesis of claim 9, wherein:

the endoprosthesis is in the form of a peripheral stent.

31. (Rejected) The endoprosthesis of claim 9, wherein:

the endoprosthesis is in the form of a balloon-expandable stent.

32. (Rejected) The endoprosthesis of claim 10, wherein:

the endoprosthesis is in the form of a self-expanding stent.

33. (Rejected) The endoprosthesis of claim 30, wherein:

the endoprosthesis is in the form of a self-expanding stent.

34. (Rejected) The endoprosthesis of claim 10, wherein:

the endoprosthesis is in the form of a balloon-expandable stent.

35. (Rejected) The endoprosthesis of claim 30, wherein:

the endoprosthesis is in the form of a balloon-expandable stent.

36. (Rejected) The endoprosthesis of claim 16, wherein:

a first plurality of the plurality of legs form leg rings and a second plurality of the plurality of legs define connecting legs that connect adjacent leg rings together,

wherein the connecting legs are of a smaller cross-sectional area or a smaller minimum diameter than the legs which form the leg rings.

37. (Rejected) The endoprosthesis of claim 17, wherein:

a first plurality of the plurality of legs form leg rings and a second plurality of the plurality of legs define connecting legs that connect adjacent leg rings together,

wherein the connecting legs are of a smaller cross-sectional area or a smaller minimum diameter than the legs which form the leg rings.

IX. EVIDENCE APPENDIX

EXHIBIT 1

Office Action dated February 7, 2008

EXHIBIT 2
U.S. Pat. No. 6,979,347

First Cited by the Examiner in an Office Action October 31, 2006

EXHIBIT 3
U.S. Pat. No. 4,401,621

First Cited by the Examiner in an Office Action August 24, 2007.

EXHIBIT 4
U.S. Pat. No. 6,676,697

First Cited by the Examiner in an Office Action October 31, 2006.

X. RELATED PROCEEDINGS APPENDIX

NONE

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,717	11/11/2003	Claus Harder	117163.00095	7255

21324 7590 02/07/2008

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EXAMINER	
TYSON, MELANIE RUANO	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
02/07/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@hahnlaw.com
akron-docket@hotmail.com

Office Action Summary	Application No.	Applicant(s)	
	10/706,717	HARDER ET AL.	
	Examiner	Art Unit	
	MELANIE TYSON	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to applicant's amendment received on 26 November 2007.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-17 and 19-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (6,979,347 B1). Wu discloses an endoprosthesis (see entire document) having a carrier structure of metallic material, wherein the metallic material comprises a magnesium alloy (for example, see column 4, lines 30-35). It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a magnesium alloy of the composition claimed, since such magnesium alloys are well known (for example, see Unsworth's patent 4,401,621; discloses magnetic alloys of such composition have good tensile properties at both ambient and elevated temperatures, and are resistant to creep while having an adequate ductility).

Furthermore, the functional language of claims 7 and 25-29 has been carefully considered, but deemed not to impose any structural limitations on the claims to make them patentably distinguishable over Wu's device, which is capable of performing the function as claimed.

Wu discloses a self-expanding or balloon expandable stent (for example, see column 3, lines 41-55) produced by cutting (for example, see column 3, lines 32-35), for use in any biological or physiological lumen (for example, column 3, lines 56-65), formed by a plurality of legs (22) and connecting elements (24), carrying an active substance (for example, see column 2, lines 1-6), and coated with a drug (for example, see column 1, lines 39-43). The legs (22) have the same suitable width (W1) and the same suitable thickness (T; column 4, lines 16-29). Since the grooves formed on the plurality of legs (22) preferably have depths less than 50% of the thickness (T) of the plurality of legs (22; column 5, lines 9-10), the ratio of largest to smallest cross-sectional area and diameter of the plurality of legs is smaller or less than 2.

4. Claims 18, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. in view of Richter (Patent No. 6,676,697 B1). Wu discloses a device as described above, where the plurality of legs (22) form rings that are connected via connecting legs (24; column 3, line 66 - column 4, line 4). However, Wu fails to disclose the connecting legs are of a smaller cross-sectional area than the plurality of legs. Richter discloses a stent having a plurality of members and connectors (Figure 1). Richter teaches that reducing the width of the connectors provides the device with greater flexibility (column 6, line 44 – column 7, line 5). Therefore, it would

have been obvious to one of ordinary skill in the art at the time the invention was made to construct the connecting legs of the device of Wu with a smaller cross-sectional area than the legs as taught by Richter in order to provide the device with greater flexibility, which in turn allows the device to accommodate the curvature of vessels.

Response to Arguments

5. Applicant's arguments filed 26 November 2007 have been fully considered but they are not persuasive. Applicant argues primarily that Unsworth fails to teach that the magnesium alloy disclosed may be useful in stents. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize such a well known magnesium alloy, as evidenced by Unsworth, in Wu's stent, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice.

Furthermore, it is well within the general knowledge of one having ordinary skill in the art to choose from a finite number of identified, predictable solutions, with a reasonable expectation of success. Wu discloses utilizing magnesium alloys for fabricating stents. Unsworth suggests a magnesium alloy encompassing the composition claimed. Unsworth teaches that magnesium alloys comprising such a composition are capable of giving good tensile properties over a wide range of temperatures, including ambient and elevated temperatures, and high resistance to creep while retaining satisfactory ductility, making them highly suitable for engineering applications (for example, see column 2, lines 13-45). Therefore, it would have been

obvious to one having ordinary skill in the art at the time the invention was made to try the well known magnesium alloy, as evidenced by Unsworth, in Wu's stent. Doing so would provide Wu's stent with the mechanical advantages described above.

With respect to the applicant's argument that neither Wu nor Unsworth teach or suggest the use of such an alloy would provide advantageous properties such as prevention of restenosis from sustained tissue growth prevention, a lack of inflammatory effect, minimize inflammation, minimize restenosis, decomposition products which have positive effect and no negative effect, and torsional strength, it is well settled that a patent cannot be granted for an applicant's discovery of a result, even though it may be unexpectedly good, which would flow logically from the teaching of the prior art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE TYSON whose telephone number is (571)272-9062. The examiner can normally be reached on Monday through Friday 9-5:30 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /MT/
January 30, 2008

/Darwin Erezo/
DARWIN EREZO
PRIMARY EXAMINER

US006979347B1

(12) **United States Patent**
Wu et al.

(10) **Patent No.: US 6,979,347 B1**
(45) **Date of Patent: Dec. 27, 2005**

(54) **IMPLANTABLE DRUG DELIVERY PROSTHESIS**

(75) Inventors: **Steven Z. Wu**, Santa Clara, CA (US); **Deborra Sanders-Millare**, San Jose, CA (US); **Sameer Harish**, Fremont, CA (US); **Ryan J. Santos**, San Jose, CA (US); **Li Chen**, San Jose, CA (US)

(73) Assignee: **Advanced Cardiovascular Systems, Inc.**, Santa Clara, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/695,022**

(22) Filed: **Oct. 23, 2000**

(51) **Int. Cl.**[7] **A61F 2/06**
(52) **U.S. Cl.** **623/1.15**; 623/1.42; 623/1.43
(58) **Field of Search** 623/1.13, 1.15, 623/1.42, 1.43, 23.57, 23.75, 1.34, 1.44; 424/423

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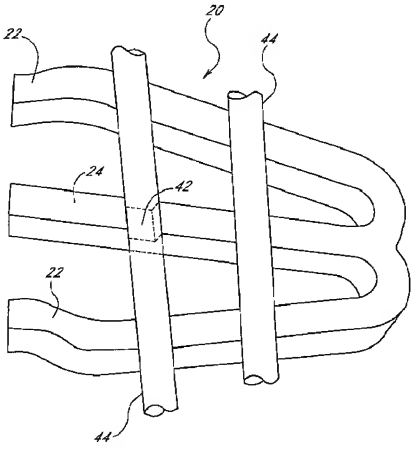
Primary Examiner—Paul B. Prebilic
(74) *Attorney, Agent, or Firm*—Squire, Sanders & Dempsey L.L.P.

(57) **ABSTRACT**

An apparatus and associated method for delivering a therapeutic substance to a vascular lumen, using an implantable prosthesis, such as a stent, which has grooves or trenches formed thereon. The grooves are formed on specific regions of the stent struts to increase the flexibility of the stent. The grooves also provide a therapeutic material carrying capability for treating intravascular ailments, such as instent restenosis and thrombosis. The therapeutic material loading of the grooves can be accomplished in several ways. For example, a pure therapeutic material or a pre-mixed material with a polymer solution, which enhances the adhesion properties of the material, may be deposited directly in to the grooves using conventional spray or modified dip techniques. In another example, a microextruded monofilament therapeutic material can be wound about the stent, such that the monofilament becomes embedded in the grooves.

32 Claims, 7 Drawing Sheets



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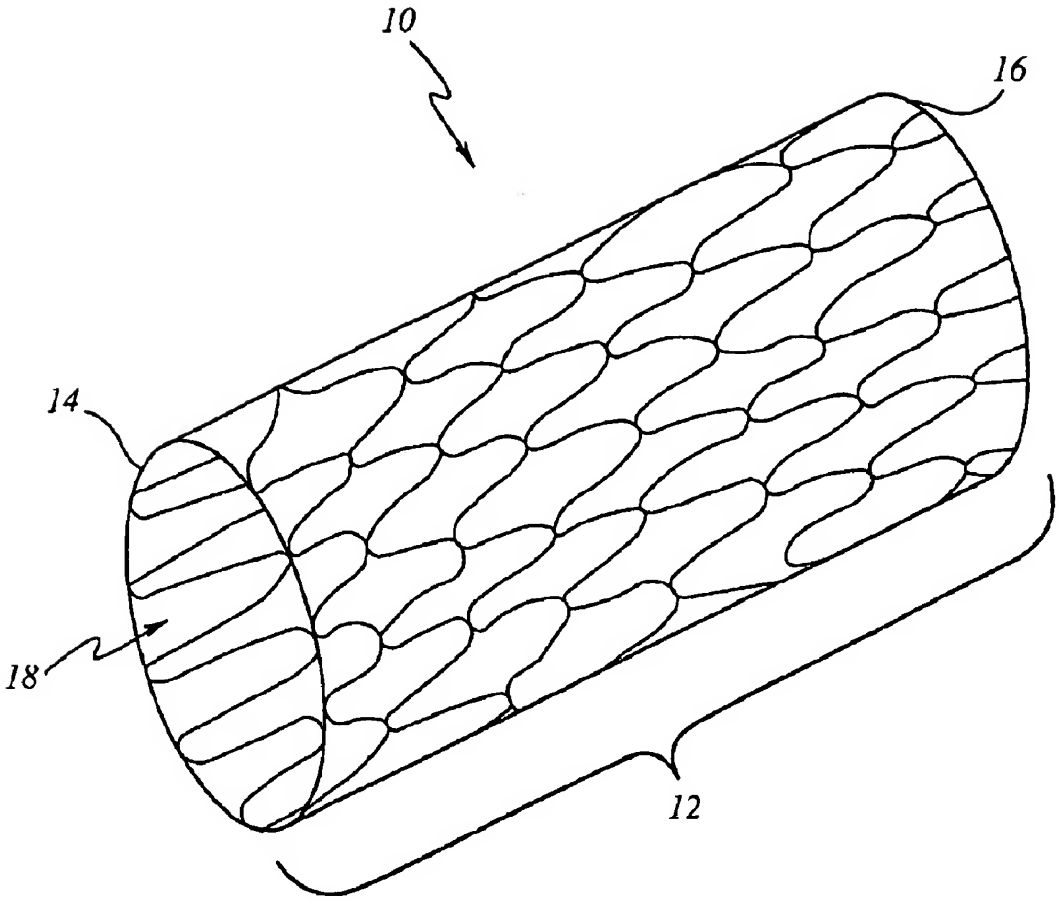

FIG. 1

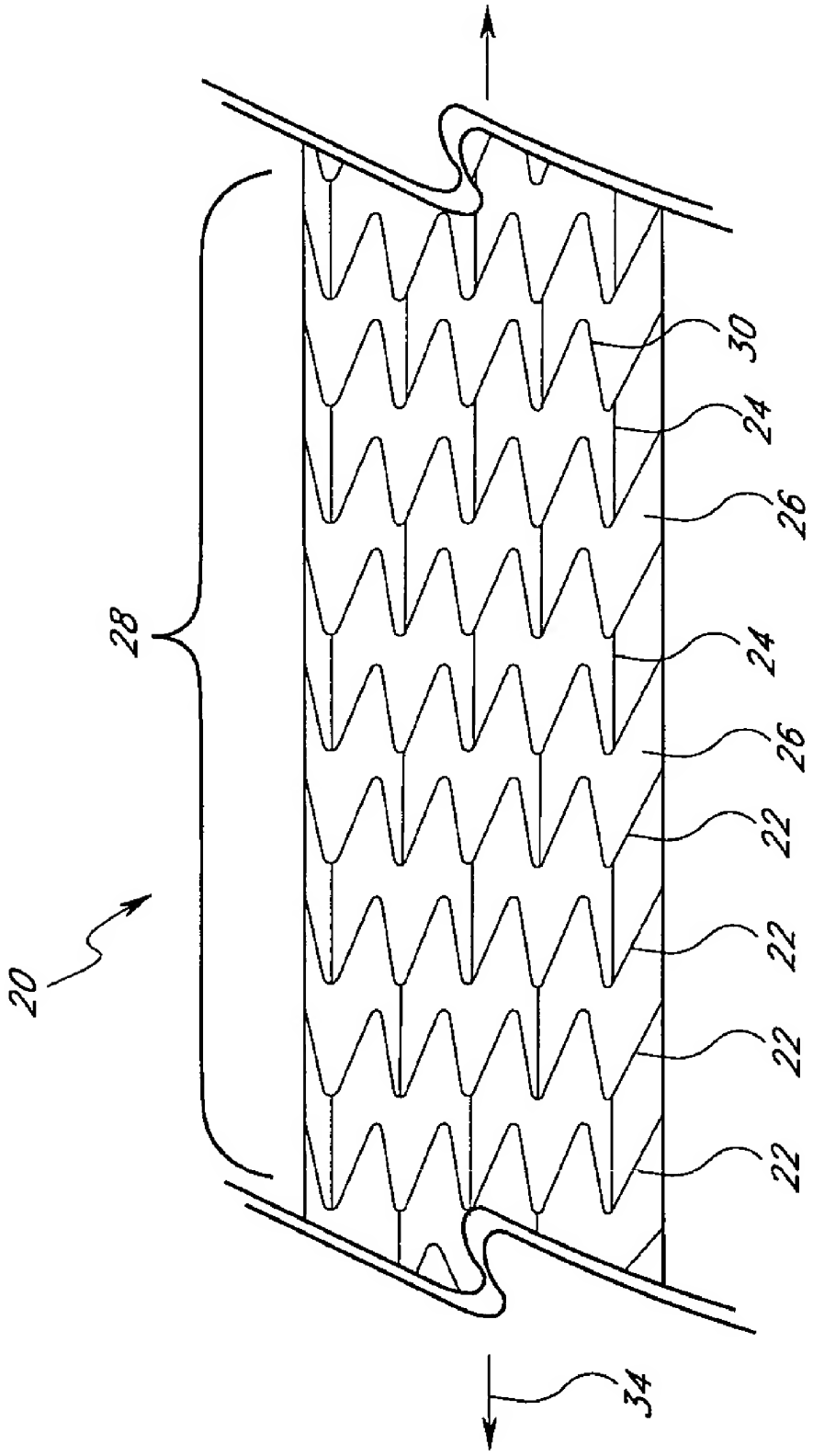

FIG. 2

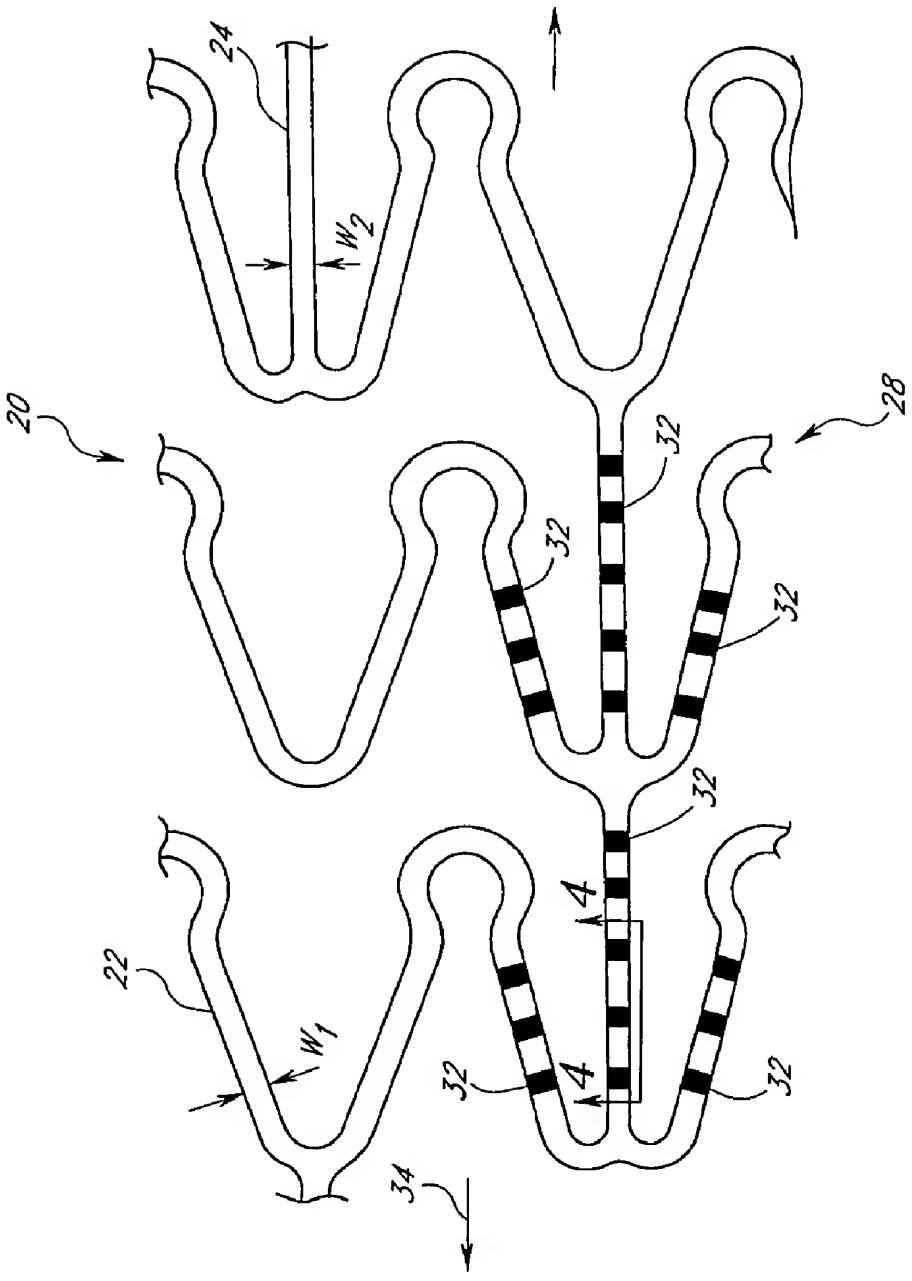

FIG. 3

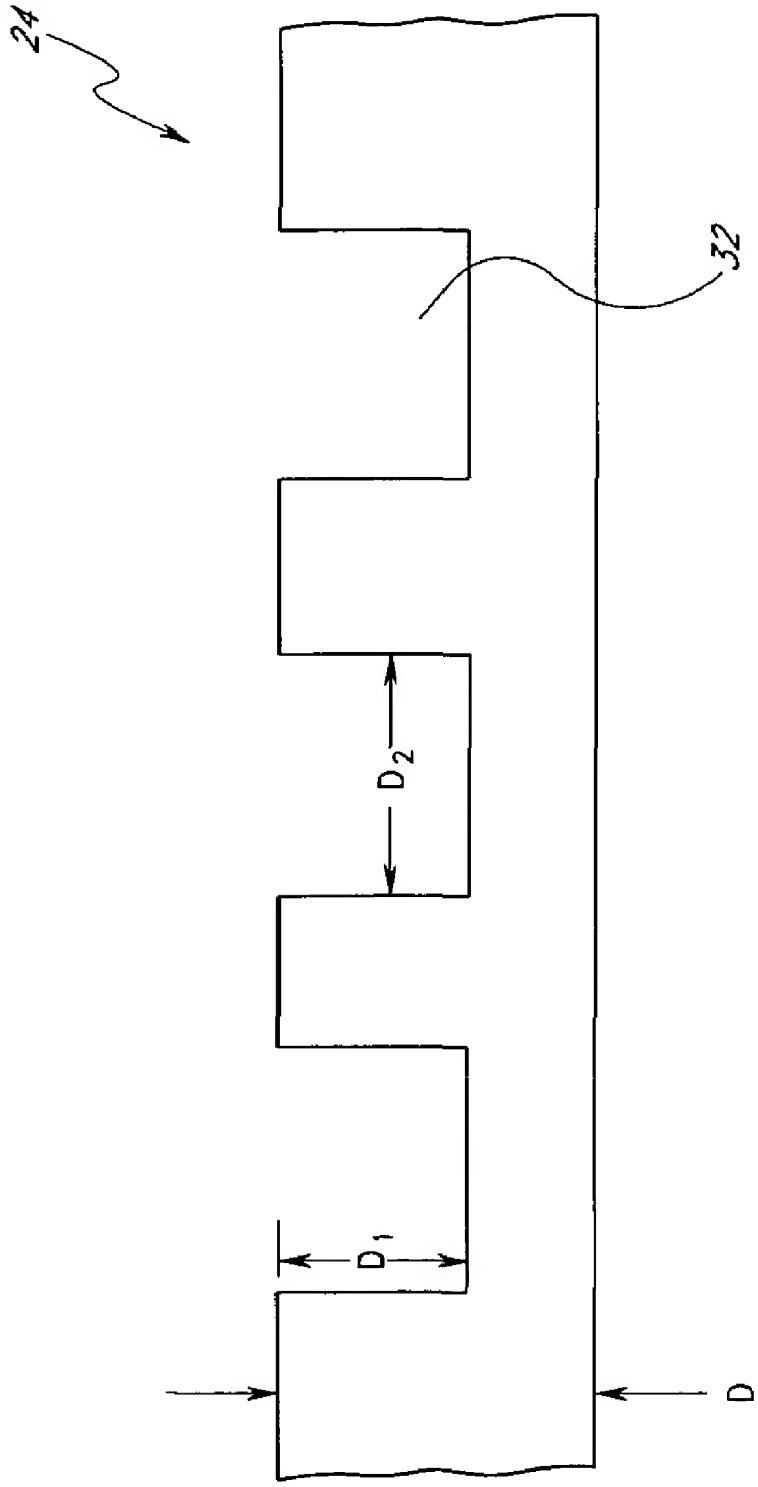

FIG. 4

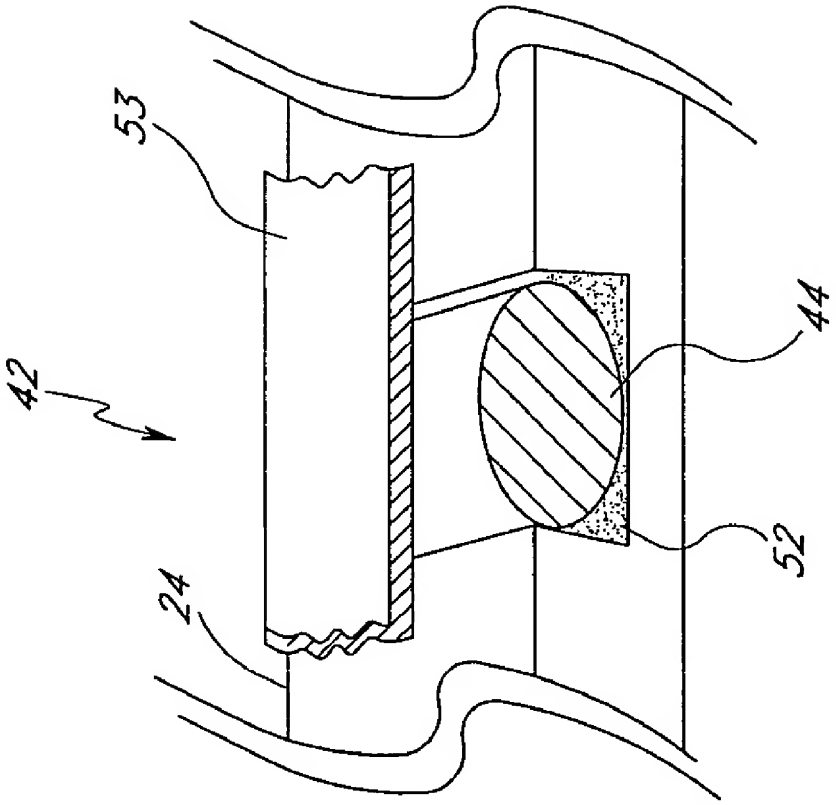

FIG.5

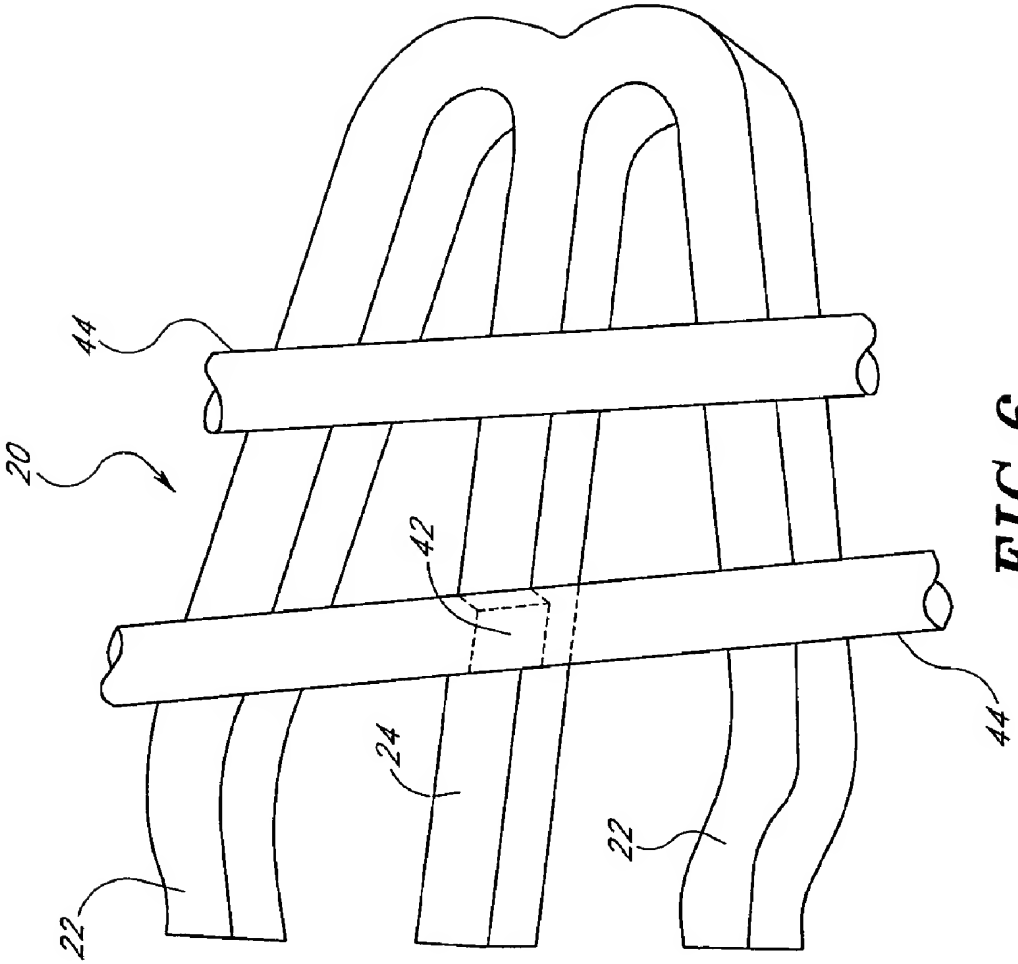

FIG. 6

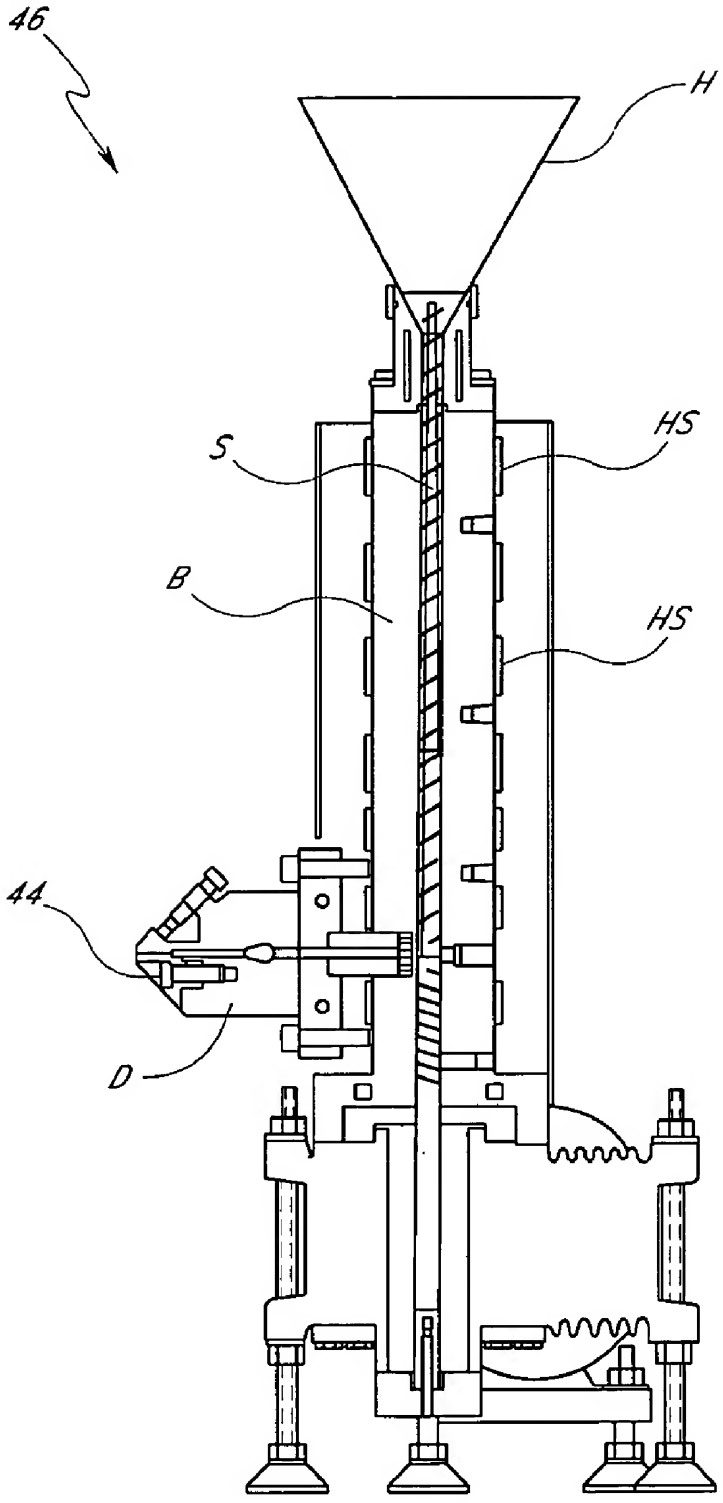

FIG. 7

IMPLANTABLE DRUG DELIVERY PROSTHESIS

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a medical device for delivering a substance to a vascular lumen. More specifically, the present invention relates to a vascular stent capable of delivering a therapeutic substance.

2. Related Art

Percutaneous transluminal coronary angioplasty (PTCA) is a procedure for treating heart disease. A catheter assembly having a balloon portion is introduced into the cardiovascular system of a patient via the brachial or femoral artery. The catheter assembly is advanced through the coronary vasculature until the balloon portion is positioned across the occlusive lesion. Once in position across the lesion, the balloon is inflated to a predetermined size to radially compress against the atherosclerotic plaque of the lesion to remodel the arterial lumen. The balloon is then deflated to a smaller profile to allow the catheter to be withdrawn from the patient's vasculature.

In treating the damaged vasculature tissue and to deter thrombosis and restenosis, therapeutic substances are commonly administered to the treatment site. For example, anticoagulants, antiplatelets and cytostatic agents are commonly used to prevent thrombosis of the coronary lumen, to inhibit development of restenosis, and to reduce post-angioplasty proliferation of the vascular tissue, respectively.

Systemic administration of such therapeutic substances in sufficient amounts to supply an efficacious concentration to the local treatment site often produces adverse or toxic side effects for the patient. Accordingly, local delivery is a preferred method of treatment since smaller total levels of medication are administered and concentrated at a specific treatment site. Local delivery thus produces fewer side effects and achieves more effective results.

A common technique for local delivery of therapeutic substances employs medicated stents. For example, a metallic stent can be coated with a polymeric material which, in turn, is impregnated with a therapeutic substance or a combination of substances. Once the stent is implanted within a cardiovascular system lumen, the drug or drugs are released from the polymer for the treatment of the local tissues. What is needed is a stent design with improved mechanical functionality and drug delivery capabilities.

SUMMARY

The present invention provides an apparatus and associated method for delivering a therapeutic substance to a vascular lumen. In accordance with one aspect of the present invention, an implantable prosthesis, such as a stent, has grooves or trenches formed thereon. The grooves can be created using either lazing or selective mechanical/chemical etching techniques. The grooves are formed on specific regions of the stent struts, such as the connecting elements (i.e., links) or connecting arm elements (i.e., arms) to increase the flexibility of the stent. For example, by forming groove patterns on the arm elements of the stent, the bending/deflecting angle of the stent can be increased. Advantageously, since the arm elements tend to inherently oppose stent/balloon expansion, lower balloon expansion pressures can be used to extend the grooved arm elements, which can reduce or prevent injury to the vascular lumen. The increased stent flexibility can also facilitate the navigation of the stent through otherwise inaccessible or tortuous pathways, which lead to lesion sites.

In accordance with another aspect of the invention, the grooves can provide a therapeutic material carrying capability for treating intravascular ailments, such as restenosis and thrombosis. The therapeutic material loading of the grooves can be accomplished in several ways. For example, as described in greater detail below, a pure therapeutic material or a pre-mixed material with a polymer solution, which enhances the adhesion properties of the material, may be deposited directly into the grooves using conventional spray or modified dip techniques.

In another example, a microextruded monofilament therapeutic material can be embedded in the grooves. The monofilament generally resembles a string, which can be wound around the outside of the stent, so that the monofilament rests in the grooves. The monofilament therapeutic material becomes embedded in the grooves or is held in the grooves using an adhesive substance. Cutting, lazing, heating and the like can remove portions of the monofilament, which lay outside of the grooves, such that only the portion of the monofilament within the groove remains on the stent. Optionally, a top or barrier coating may be applied over the therapeutic monofilament embedded grooves to create a controllable release rate barrier.

Advantageously, the grooved stent can be deployed within the human vasculature with little or no significant loss of the therapeutic substance from the stent during delivery and expansion of the stent. The monofilament structure also provides for increased control of the release rate of the therapeutic substance from the stent.

In accordance with yet another aspect of the invention, an implantable prosthesis is provided including a tubular body structure including support elements separated by gaps; grooves disposed in said support elements; and a string strong enough to be circumferentially wrapped exclusively around the outer perimeter of said body structure of said implantable prostheses, said string being disposed in said grooves of at least some of said support elements such that said grooves act as guides for allowing said string to be circumferentially supported by said body structure, and wherein said string extends across said gaps between said support elements when circumferentially supported by said body structure.

Uses, advantages, and variations of the present invention will be apparent to one of ordinary skill in the art upon reading this disclosure and accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a simplified perspective view of a typical intraluminal prosthesis in accordance with an embodiment of the present invention;

FIG. **2** is a simplified side view of a portion of an intraluminal prosthesis, the body of the prosthesis being defined by cylindrical elements engaged to one another by connecting elements;

FIG. **3** is a close-up view of a portion of the intraluminal prosthesis of FIG. **2**;

FIG. **4** is a cross sectional view along the line **4**—**4** of FIG. **3**;

FIG. **5** is a partial close-up view of a groove loaded with a substance in accordance with one embodiment of the invention;

FIG. **6** is a simplified illustration of an implantable prosthesis; and

FIG. **7** is an illustration of a microextruder.

The features of the described embodiments are specifically set forth in the appended claims. However, embodiments relating to both structure and method are best understood by referring to the following description and accompanying drawings, in which similar parts are identified by like reference numerals.

DETAILED DESCRIPTION

Stent deployment can result in early thrombus deposition and acute inflammation, granulation tissue development, and ultimately smooth muscle cell proliferation and extracellular matrix synthesis. The severity of arterial injury during stent placement correlates with increased inflammation in late neointimal growth. The progression of intimal thickening with time after experimental stent-induced vascular injury and clinical stent placement is well characterized. Experimental and clinical studies of endovascular stenting have demonstrated a complex network of vascular responses including thrombosis, neointimal hyperplasia, and inflammation. An implantable prosthesis can deliver a therapeutic substance designed to treat the various vascular responses to injury.

Referring now to the drawings, wherein similar parts are identified by like reference numerals, FIG. **1** illustrates a typical implantable prosthesis **10**. Implantable prosthesis **10** includes a body structure **12** defined by an elongated tubular body having a first end **14**, a second end **16**, and a hollow lumen **18** extending therebetween. In one embodiment, implantable prosthesis **10** is an implantable stent. A typical implantable stent may take many shapes and forms and be of a variety of lengths. For example, the implantable stent may be a cylindrical tube that has had a pattern of rings and connecting elements formed thereon either, for example, by laser cutting, cutting or etching. The rings and connecting elements of the stent may be of a variety of thickness and lengths. Typically, an implantable stent can range in length from about 5 mm to about 50 mm. The actual physical dimensions of the implantable stent are dependent on the application.

Generally, an implantable stent is deployed in a physiological lumen from a radially compressed configuration into a radially expanded configuration which allows the stent to contact and support the physiological lumen. The stent is deformable such that it can be made to be radially self-expanding or expandable by the use of an expansion device. The self-expanding stent can be made from a resilient springy material while the device expandable stent can be made from a material which is plastically deformable. A plastically deformable stent can be implanted during an angioplasty procedure by using a balloon catheter. The deformable stent radially expands as the balloon is inflated, forcing the stent into contact with the interior of the physiological lumen thereby forming a supporting relationship with the lumen walls.

In accordance with one embodiment, implantable prosthesis **10** provides for delivery of a substance, such as a therapeutic substance or a combination of therapeutic substances, to a desired area of a vascular lumen in order to treat a localized area of the vascular lumen. It is contemplated that implantable prosthesis **10** has applicability for use with any biological or physiological lumen, for example, blood vessels, urinary tract lumen, intestinal tract lumen, kidney ducts, wind pipes, the vas deferens, ducts of the gallbladder, prostate gland, trachea, bronchus, liver and the like.

As illustrated FIG. **2**, in one embodiment, stent **20** can include a plurality of arm elements **22** that are arranged in a configuration that is connected to form a continuous ring or cylinder. The plurality of cylindrical arm elements **22** are radially expandable, disposed coaxially, and interconnected by connecting elements or links **24**. Connecting elements **24** are disposed between adjacent cylindrical arm elements **22**, leaving gaps or lateral openings **26** between adjacent cylindrical arm elements **22**. Although the arm elements **22** are illustratively shown in the form of cylinders or rings connected axially and displaced in-parallel, other configurations, such as helices, coils, or braids, and other connections may be used. Arm elements **22** and connecting elements **24** define a tubular stent body **28** having a lumen contacting surface **30**. Lumen contacting surface **30** includes the outwardly exposed surface portions of arm elements **22** and connecting elements **24**.

FIG. **3** is a close-up view of a portion of stent **20**. Arm elements **22** have any suitable width W_1, typically in a range of width W_1 from about 0.05 mm to about 0.2 mm. A common width W_1 is about 0.08 mm. Connecting elements **24** have any suitable width W_2, typically in a range of width W_2 from about 0.05 mm to about 0.2 mm. A common width W_2 is about 0.12 mm. Additionally, arm elements **22** and connecting elements **24** have any suitable thickness, typically a thickness in a range from about 0.05 mm to about 0.2 mm. A common thickness T (FIG. **4**) is about 0.12 mm. A specific choice of width and thickness depends on the anatomy and size of the target lumen. Thus, the size of the stent can vary according to intended procedure, anatomy, and usage.

Arm elements **22** and connecting elements **24** are typically fabricated from a metallic material or an alloy, such as stainless steel (e.g., 316L), MP35N, MP20N, tantalum, nickel-titanium alloy (commercially available as Nitinol™), platinum-iridium alloy, gold, magnesium, or combinations of alloys. MP35N and MP20N are trade names for alloys of cobalt, nickel, chromium and molybdenum available from standard Press Steel Co., Jenkintown, Pa. MP35N has a nominal composition of 35% cobalt, 35% nickel, 20% chromium, and 10% molybdenum. MP20N has a nominal composition of 50% cobalt, 20% nickel, 20% chromium, and 10% molybdenum.

As illustrated in FIG. **3**, a single groove or channel **32** or plurality of grooves or channels **32** are formed as an open ended trench or trenches into arm elements **22** and/or connecting elements **24**. In one embodiment, channels **32** are formed or cut across arm element **22** and/or connecting element **24**, such that channels **32** are formed substantially perpendicular to a central axis **34** of stent **20**, when stent **20** is in a collapsed configuration. It should be understood that as stent **20** expands, grooves **32** may change angle relative to central axis **34**.

Grooves **32** can be formed by any well-known method of cutting or removing material, for example, by exposing arm elements **22** and/or connecting elements **24** to an energy discharge from a laser, such as a YAG laser or excimer laser. Alternative methods of forming grooves **32** include physical or chemical etching techniques. Techniques of laser fabrication or etching to form grooves **32** are well-known to one of ordinary skill in the art. Grooves **32** can be formed in virtually any stent structure and not merely the above-described structure.

The location or placement of grooves **32** on arm elements **22** and connecting elements **24** can vary according to the intended usage and application of stent **20**. In one example, grooves **32** are evenly distributed over body **28** and have an equal volume so that the tissue in contact with stent **20** receives an equal distribution of a therapeutic substance.

Grooves **32** can be formed to any suitable open-ended geometrical configuration, for example, a rectangular channel, which can have any preselected depth and size. As illustrated in FIG. **4**, depth D_1 of groove **32** can be varied in proportion to the thickness T of connecting element **24** or arm element **22** depending on the clinical purpose and usage. In one embodiment, a suitable groove or channel depth D_1 has a range from about 10% to about 90% of thickness T. Typically, a depth not greater than about 50% of thickness T is most suitable. The specific depth D_1 of groove **32** depends on the amount of therapeutic substance that is to be deposited. In one example of stent **20** carrying a radioactive isotope, depth D_1 is typically about 10% to about 80% of thickness T. A more specific suitable depth is not greater than about 30% of thickness T. In another example, stent **20** carrying a radiopaque material, a suitable groove or channel **32** depth D_1 has a range from about 10% to about 90% of thickness T. Typically, a depth not greater than about 65% is most suitable. The upper limit of depth D_1 varies depending on the material characteristics, such as the hardness of the structural material used in stent **20**.

Referring again to FIG. **4**, groove **32** can have a breadth D_2, which can range from about 0.03 mm to about 0.18 mm, although the breadth D_2 is usually not greater than about 0.13 mm. The specific breadth D_2 depends on the application and purpose of the grooves **32**. The upper limit of the breadth D_2 varies depending on the material characteristics of stent **20**, such as the hardness of the structural material used in stent **20**.

Although grooves **32** have been illustrated in FIG. **4** as having a substantially rectangular cross-section, it is anticipated that the actual shape of groove **32** can vary. For example, groove **32** may have a circular cross-section (cylindrical groove) having a diameter dependent on the application and purpose of the groove. Other grooves may be formed with triangular, oval, and other similar geometry.

Referring again to FIG. **3**, grooves **32** are substantially aligned in axially displaced rows of grooves **32**, where each row extends across stent **20** nearly perpendicular to axis **34**. In one embodiment, for a given width W_1 or W_2, the depth D_1 and breadth D_2 (i.e., the volume) of each groove **32** in a row of grooves **32** on stent **20** can vary relative to other grooves in other rows of grooves **32**. In one example, the manufacturer selectively controls the volume of grooves in a row on different positions of body **28**, either selectively varying the volume between rows or making the volume consistent throughout body **28**. For some applications, consistent groove volume provides evenly distributed therapeutic material delivery throughout stent **20** and results in consistent application of the therapeutic substance to the tissues in contact with surface **30** of stent **20**.

In some embodiments, the therapeutic substance or agent, can include antineoplastics, anti-inflammatory substances, antiplatelets, anticoagulants, fibrinolytics, thrombin inhibitors, antimitotics, and antiproliferatives. Examples of antineoplastics include paclitaxel and docetaxel. Examples of antiplatelets, anticoagulants, fibrinolytics, and thrombin inhibitors include sodium heparin, low molecular weight heparin, hirudin, argatroban, forskolin, vapiprost, prostacyclin and prostacyclin analogues, dextran, D-phe-pro-arg-chloromethylketone (synthetic antithrombin), dipyridamole, glycoprotein IIb/IIIa platelet membrane receptor antibody, recombinant hirudin, thrombin inhibitor (available from Biogen), and 7E-3B® (an antiplatelet drug from Centocore). Examples of suitable antimitotic agents include methotrexate, azathioprine, vincristine, vinblastine, flurouracil, adriamycin, mutamycin and actinomycin D. Examples of suitable cytostatic or antiproliferative agents include angiopeptin (a somatostatin analogue from Ibsen), angiotensin converting enzyme inhibitors such as Captopril® (available from Squibb), Cilazapril® (available from Hofman-LaRoche), or Lisinopril® (available from Merck); calcium channel blockers (such as Nifedipine), colchicine, fibroblast growth factor (FGF) antagonists, fish oil (omega 3-fatty acid), histamine antagonist, Lovastatin® (an inhibitor of HMG-CoA reductase, a cholesterol lowering drug from Merck), monoclonal antibodies (such as PDGF receptors), nitroprusside, phosphodiesterase inhibitors, prostaglandin inhibitor (available form Glazo), Seramin (a PDGF antagonist), serotonin blockers, steroids, thioprotease inhibitors, triazolopyrimidine (a PDGF antagonist), and nitric oxide. Other therapeutic substances or agents which may be appropriate include alphainterferon, genetically engineered epithelial cells, and dexamethasone.

While the listed therapeutic substances or agents are well known for preventative and therapeutic utility, the substances are listed by way of example and are not meant to be limiting. Other therapeutic substances which are currently available or that may be developed in the future are equally applicable. The treatment of patients using the above mentioned medicines is well-known to those of ordinary skill in the art.

In other embodiments, the therapeutic material can be a radioactive isotope for stent usage in radiotherapeutic procedures. Examples of radioactive isotopes include, but are not limited to, phosphoric acid ($H_3P^{32}O_4$), palladium (Pd^{103}), cesium (Cs^{131}), and iodine (I^{125}).

FIG. **5** and FIG. **6** illustrate an embodiment for therapeutic substance loading in accordance with the present invention. In this embodiment, the therapeutic material can be dissolved or otherwise embedded into a polymer material, which is microextruded into a monofilament **44**. Monofilament **44** is subsequently loaded onto stent **20**.

Monofilament **44** can be formed using any conventional microextrusion extruder, for example, the microextruder of the type illustrated in FIG. **7**, available commercially from RANDCASTLE Extrusion Systems, Inc., of Cedar Grove, N.J. In this example, extruder **46** includes an extrusion screw S, which is driven from a drive end located at the upstream end of extrusion screw S. Hopper pellets of a polymeric material, as described below, are introduced into the hopper barrel H within which extrusion screw S is rotationally mounted. The therapeutic material can be added into hopper H to mix with the hopper pellets. Therapeutic parameters such as the concentration of the therapeutic substance in monofilament **44** and dosages depend on the duration of local release, the cumulative amount of release, and desired rate of release. Correlation and interrelation between the therapeutic parameters are well-known to one having ordinary skill in the art and are simply calculated. For example, polymer pellets of polyuethene can be mixed at a ratio of 10–30% of dexamethasone.

The hopper pellets and therapeutic substance are conveyed together downstream through barrel B and melted into molten polymer using heaters HS. It should be understood that in selecting both the polymer and therapeutic substance, the melting point of the polymer and the degradation temperature of the therapeutic substance should correlate such that the stability of the therapeutic substance is maintained. For example, the therapeutic substances b-estradiol, Vincristine and Colchicine, have degradation temperature limits of about 200° C., 60° C. and 200° C., respectively. These substances should be used with polymers having melting point temperatures lower than their degradation tempera-

tures. For example, ethylene vinyl alcohol, which has a melting point of 160° C. and low-density polyethylene, which has a melting point of 120° C., may be used with b-estradiol and Colchicine, while polyethylene glycol, which has a melting point of about 50° C., may be used with Vincristine. Correlation and interrelation between the therapeutic temperature parameters and the polymer temperature parameters are well-known to one having ordinary skill in the art and are simply planned.

The medicated melted polymer is discharged to an extrusion die D to form monofilament **44**. The general dimensions of monofilament **44** are such that they substantially conform to the dimensions of grooves **32** (FIG. **3**).

In one embodiment, monofilament **44** is processed to resemble a "string." As shown in FIG. **6**, string monofilament **44** can be wrapped around the outside surface **30** of stent **20**, such that monofilament **44** comes to rest in the grooves, such as groove **42** (shown in phantom). In one embodiment, a liquid polymer **52** (FIG. **5**) may be used to attach certain areas of monofilament **44** to stent **20**. Liquid polymer **52** may be, for example, a medical adhesive, such as those available from Master Bond, Inc. of Hackensack, N. J. In another embodiment, monofilament **44** can be sized such that monofilament **44** is force fit into the grooves.

Once monofilament **44** is disposed within the grooves, a laser can be used to cut and remove portions of monofilament **44** which are not held within the grooves. Alternatively, a heat source can be brought proximate to stent **20**, such that portions of monofilament **44** that are not held within the grooves can melt or dissolve away. As illustrated in FIG. **5**, monofilament **44** remains in channel **42** until prosthesis deployment and expansion. The expanded prosthesis engages the wall of the anatomical lumen and the therapeutic substance is absorbed into the tissue of the walls of the body lumen that are in contact with prosthesis surface **30** (FIG. **2**).

In one embodiment, stent **20** can be coated with a therapeutic substance in addition to having a therapeutic substance deposited in channels **32**. The therapeutic substance is a substance that is capable of absorbing or attaching to the prosthesis surface. For example, highly suitable therapeutic substances for a stainless steel prosthesis include paclitaxel and dexamethasone, substances that easily attach to a metallic substrate.

In another embodiment, a polymeric coating **53** (FIG. **5**) can be formed on the surface of the prosthesis covering the channel. In this embodiment, coating **53** covers channel **42** containing the deposited therapeutic substance monofilament **44**. Polymeric coating **53** forms a membrane that reduces the rate of release of a therapeutic substance from the channel.

In the embodiments, polymeric monofilament **44** is suitably bio-compatible, non-toxic, non-inflammatory, chemically inert, and substantially non-immunogenic. Monofilament **44** can be typically either bioabsorbable or biostable. A bioabsorbable polymer bio-degrades or breaks down in the body and is not present sufficiently long after implantation to cause an adverse local response. Bioabsorbable polymers are gradually absorbed or eliminated by the body by hydrolysis, metabolic process, bulk, or surface erosion. Examples of bioabsorbable biodegradable materials include but are not limited to polycaprolactone(PCL), poly-D,L-lactic acid(DL-PLA), poly-L-lactic acid(L-PLA), poly(lactide-co-glycolide), poly(hydroxybutyrate), poly(hydroxybutyrate-co-valerate), polydioxanone, polyorthoester, polyanhydride, poly(glycolic acid), poly(glycolic acid-cotrimethylene carbonate), polyphosphoester, polyphosphoester urethane, poly (amino acids), cyanoacrylates, poly (trimethylene carbonate), poly(iminocarbonate), copoly (ether-esters), polyalkylene oxalates, polyphosphazenes, polyiminocarbonates, and aliphatic polycarbonates. Examples of biostable polymers include Parylene®, Parylast® polyurethane (for example, segmented polyurethanes such as Biospan®), polyethylene, polyethylene terephthalate, ethylene vinyl acetate, silicone and polyethylene oxide. Biomolecules such as heparin, fibrin, fibrinogen, cellulose, starch, and collagen represent other substances which can be used to coat, or alternatively can be embedded into the biostable polymer.

While particular embodiments of the present invention have been shown and described, it will be obvious to those having ordinary skill in the art that changes and modifications can be made without departing from this invention in its broader aspects. For example, although a particular stent shape with particular arm elements and connecting elements is described herein, those having ordinary skill in the art would recognize that other stent shapes could be used as well, including a tubular stent. Those having ordinary skill in the art would also recognize that although coronary applications are described herein, Applicants' implantable prosthesis can be any type of stent, including peripheral or neurological stents. Therefore, the appended claims are to encompass within their scope all such changes and modifications as fall within the scope of the invention.

What is claimed is:

1. An implantable prosthesis, comprising:

a body structure having an outer surface for contacting a surface of a lumen;

a plurality of grooves disposed on said outer surface of said body structure of said implantable prosthesis; and

a continuous string having a therapeutic substance, said string resting in a plurality of said grooves, wherein said string is capable of being wound around said body structure.

2. The implantable prosthesis of claim **1**, wherein a depth of said grooves is equal to about 10% to 90% of a thickness of said body structure.

3. The implantable prosthesis of claim **1**, wherein a depth of said grooves is not greater than about 65% of a thickness of said body structure.

4. The implantable prosthesis of claim **1**, wherein said string comprises a polymer material.

5. The implantable prosthesis of claim **1**, wherein said therapeutic substance comprises a substance selected from the group consisting of antineoplastic, antiplatelet, anticoagulant, fibrinolytic, antimitotic, thrombin inhibitor, antiinflammtory, and antiproliferative agents.

6. The implantable prosthesis of claim **1**, wherein said therapeutic substance comprises a radioactive isotope.

7. The implantable prosthesis of claim **1**, further comprising a barrier disposed on said outer surface of said body structure and on said string to reduce the rate at which said therapeutic substance is released.

8. The implantable prosthesis of claim **1**, wherein said body structure comprises a radially expandable tubular structure.

9. The implantable prosthesis of claim **1**, wherein said body structure includes arm elements joined by connecting elements.

10. The implantable prosthesis of claim **1**, additionally including an adhesive material capable of bonding said string in said grooves.

11. The implantable prosthesis of claim 1, wherein a thickness of said string is generally equivalent to a width of said grooves so as to provide a tight fit between said string and said grooves.

12. The implantable prosthesis of claim 1, wherein a thickness of said string is generally equivalent to a depth of said grooves such that said string does not protrude out from said grooves.

13. The implantable prosthesis of claim 1, wherein said string is a monofilament.

14. The implantable prosthesis of claim 1, wherein said string is made at least in part from a polymeric material.

15. The implantable prosthesis of claim 1, wherein said string comprises a filament.

16. The implantable prosthesis of claim 1, wherein said string comprises an extruded filament.

17. The implantable prosthesis of claim 1, further comprising:

an adhesive material disposed on said body structure or on said string or both.

18. An implantable prosthesis, comprising:

tubular body structure including support elements separated by gaps;

grooves disposed in said support elements; and

a string including a therapeutic substance, said string strong enough to be circumferentially wrapped exclusively around the outer perimeter of said body structure of said implantable prosthesis, said string being disposed in said grooves of at least some of said support elements such that said grooves act as guides for allowing said string to be circumferentially supported by said body structure, and wherein said string extends across said gaps between said support elements when circumferentially supported by said body structure.

19. The implantable prosthesis of claim 18, wherein a depth of said grooves is equal to about 10% to 90% of a thickness of said support elements.

20. The implantable prosthesis of claim 18, wherein a depth of said grooves is not greater than about 65% of a thickness of said support elements.

21. The implantable prosthesis of claim 18, wherein said string comprises a polymer material.

22. The implantable prosthesis of claim 18, wherein said therapeutic substance comprises a substance selected from the group consisting of antineoplastic, antiplatelet, anticoagulant, fibrinolytic, antimitotic, thrombin inhibitor, antiinflammatory, and antiproliferative agents.

23. The implantable prosthesis of claim 18, wherein said therapeutic substance comprises a radioactive isotope.

24. The implantable prosthesis of claim 18, further comprising a barrier disposed on an outer surface of said body structure and on said string to reduce the rate at which said therapeutic substance is released.

25. The implantable prosthesis of claim 18, wherein said body structure comprises a radially expandable tubular structure.

26. The implantable prosthesis of claim 18, wherein said support elements comprise arm elements joined by connecting elements.

27. The implantable prosthesis of claim 18, additionally including an adhesive material capable of bonding said string in said grooves.

28. The implantable prosthesis of claim 18, wherein a thickness of said string is generally equivalent to a width of said grooves so as to provide a tight fit between said string and said grooves.

29. The implantable prosthesis of claim 18, wherein a thickness of said string is generally equivalent to a depth of said grooves such that said string does not protrude out from said grooves.

30. The implantable prosthesis of claim 18, wherein said string is a monofilament.

31. An implantable prosthesis, comprising:

a body structure including support elements separated by gaps;

grooves disposed in said support elements; and

a continuous string including a therapeutic substance, said string disposed in said grooves of at least some of said support elements such that said grooves act as guides for allowing said string to be supported by said body structure of said implantable prosthesis, wherein said string extends across said gaps between said support elements when supported by said body structure.

32. The implantable prosthesis of claim 31, wherein said implantable prosthesis is a stent.

* * * * *

United States Patent [19]

Unsworth et al.

[11] **4,401,621**

[45] **Aug. 30, 1983**

[54] **MAGNESIUM ALLOYS**

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[57] **ABSTRACT**

Magnesium alloys for castings having good tensile properties at both ambient and high temperatures and good resistance to creep contain 1.5–10% of yttrium or an yttrium/heavy rare earths mixture and 1–6% of neodymium or a neodymium/lanthanum/praseodymium mixture. The alloys may be heat treated to improve their properties.

17 Claims, No Drawings

MAGNESIUM ALLOYS

This invention relates to magnesium alloys suitable for use in castings containing yttrium and neodymium.

Cast magnesium alloys are used in aerospace applications where good mechanical properties at both ambient and elevated temperatures are required. For example magnesium alloy components in an aero engine or helicopter rotor drive gearbox may have to retain their strength and also resist creep at a temperature of 200° C. or above. Existing magnesium alloys for such uses contain appreciable amounts, typically about 1.5–2.5% by weight, of silver. Silver is an expensive component and its price is subject to wild fluctuations for reasons associated with its use as a currency. Magnesium alloys containing silver have a lower resistance to corrosion than silver free magnesium alloys.

The present invention is intended to provide magnesium alloys capable of giving castings which have good tensile properties at both ambient and elevated temperatures, and are resistant to creep while having an adequate ductility, but which do not contain large amounts of silver.

According to one aspect of the invention, there is provided a magnesium alloy containing, apart from normal impurities,

(a) from 1.5 to 10% by weight of an yttrium component consisting of at least 60% by weight of yttrium and the balance, if any, of heavy rare earth metals, and

(b) from 1 to 6% by weight of a neodymium component consisting of at least 60% by weight of neodymium, not more than 25% by weight of lanthanum and substantially all the balance, if any, of prasecdymium,

the remainder of the alloy consisting of magnesium. The alloy may contain zirconium as a grain refiner, for example in an amount up to 1% and typically around 0.4%.

It should be noted that yttrium is not considered herein as a rare earth metal as it is not a member of the lanthanide series.

The yttrium component any consist of pure yttrium but as this is an expensive material it is preferred to use a mixture containing at least 60% yttrium and the remainder heavy rare earth metals. A "heavy rare earth metal" is a rare earth metal having an atomic number of 62 or above. The yttrium content of the yttrium component may be at least 62% and is preferably at least 75%.

The neodymium component may consist of 100% neodymium but as purification of neodymium to this level is grossly expensive it is preferred to use a mixture containing at least 60% of neodymium and up to 25% by weight of lanthanum with any balance being praseodymium: the mixture thus contains substantially no cerium.

It will be understood that when the yttrium and/or neodymium components contain rare earth metal mixtures as stated above identical alloys are obtained by adding the yttrium and/or the neodymium to the alloy melt as pure metals and adding rare earth metals separately, or by adding the yttrium and neodymium as mixtures containing the rare earth metals. Alloys made by both methods are to be considered as within the scope of this invention, the terms "yttrium component" and "neodymium component" relating to the composition of the alloy and not to the manner in which the

constituents of the alloy are added to the melt. However, in practice the yttrium would normally be added to the alloy together with the heavy rare earth metals (if any) and the neodymium would be added with the above-specified rare earth metals of the neodymium component.

The content of yttrium component may be from 1.5 to 9% and the neodymium component may contain not more than 10% of lanthanum.

In an embodiment of the invention the total content of yttrium component and neodymium component is from 4 to 14%.

Alloys within the invention are capable of giving good tensile properties over a wide range of temperatures and high resistance to creep while possessing adequate ductility. It has been found that within the composition range specified above particular contents of yttrium and neodymium components are capable of producing specific desirable combinations of properties. Thus, according to one embodiment of the invention the content of yttrium component is 2.5–7%, that of neodymium component is 1.5–4% and the total content of yttrium component and neodymium component is 6–8.5%. Alloys within this range give high tensile properties both at mbient and elevated temperatures at least equivalent to those obtained from currently available silver-containing high strength magnesium alloys.

According to another embodiment the yttrium component content is from 3.5 to 9% and the neodymium component content 2.5 to 5%, the total yttrium and neodymium components being from 7.5 to 11.5%. Alloys within this range give very good mechanical properties (including resistance to creep) at elevated temperatures up to 300° C. or higher, accompanied by a lower ductility compared with other alloys within the invention. Especially good properties are obtained in the absence of zirconium in the alloys of this embodiment.

According to yet another embodiment the yttrium component content is from 3.5 to 8%, a neodymium component 2 to 3.5% and the total of yttrium and neodymium components 7–10%. Alloys within this range have favourable mechanical properties at ambient and elevated temperatures while retaining satisfactory ductility, making them highly suitable for engineering applications.

Other elements which may be incorporated in the alloy are up to 1% of cadmium or not more than 1% of silver or up to 0.15% of copper. One or more of the following constituents may also be present in amounts consistent with their solubilities:

Thorium—0–1%
Lithium—0–6%
Gallium—0–2%
Indium—0–2%
Thallium—0–5%
Lead—0–1%
Bismuth—0–1%
Manganese—0–2%

Zinc should be substantially absent as zinc combines with yttrium to form a stable intermetallic compound with yttrium, nullifying the effect of the yttrium in the compound.

The alloys of the invention may be made by conventional methods. As the metals of the yttrium component generally have relatively high melting points they are preferably added to the melt in the form of a hardener alloy consisting of magnesium and a high proportion of the metals to be added. The neodymium component

may also be added in the form of a magnesium hardener alloy. When melting is carried out by the techniques normally used for magnesium alloys, i.e. under a protective flux or a protective atmosphere such as CO_2/SF_6 or air/SF_6 undesirable losses of yttrium, by reaction with the flux or preferential oxidation, may occur. It is therefore preferred to carry out melting under an appropriate inert atmosphere, such as argon.

The alloys of the invention may be cast by conventional methods to form cast articles. The castings generally require heat treatment to give optimum mechanical properties. One type of heat treatment comprises solution heat treatment, preferably at the highest practicable temperature (normally about 20° C. below the solidus temperature of the alloy) followed by quenching and ageing at an elevated temperature. An example of a suitable heat treatment comprises holding the casting at 525° C. for 8 hours followed by rapid quenching in a suitable medium such as water or an aqueous solution of a quench moderating agent such as UCON, and then ageing at about 200° C. for 20 hours. However it has been found that ageing at elevated temperature for a longer period, for example up to 144 hours, can give increased tensile properties for at least some of the alloys of the invention.

It has also been found that simpler heat treatments can improve the properties of the as-cast alloy. The cast alloy may be aged, for example at 200° C. for 20 hours, without solution heat treatment or quenching and the strength of the alloy is considerably increased and a good level of ductility is achieved.

Alloys according to the present invention, together with other alloys given for comparison, will be described in the following Examples.

EXAMPLES

Alloys of magnesium having the added elements given in Table 1 were cast into test specimens and the specimens were heat treated as shown in Table 1. The Nd component, indicated in the tables simply as "Nd" was a rare earth mixture containing at least 60% by weight of neodymium, substantially no cerium, up to 10% lanthanum and the remainder praseodymium. The yttrium component indicated as "Y" was pure yttrium unless otherwise stated. The yield stress, ultimate tensile stress and elongation were measured at room temperature by standard methods and the results are given in Table 1. These properties were also measured at 250° C. for some of the alloys and the results are given in Table 2. The results for known magnesium alloys QE 22 and QH 21, which contain 2.5% silver but no yttrium, are given for comparison.

The mechanical properties of some alloys were also measured at temperatures above 250° C. and the results are shown in Table 3. Room and high temperature results for a further alloy, No. 16, are shown in Table 4 in which "HRE" refers to heavy rare earthf metals: in this alloy the yttrium and heavy rare earth metals were added as a mixture.

Other alloys were cast, heat treated and tested in the same way at 20°, 250°, 300°, 325° and 350° C. and the results are shown in Table 5. Comparative results are given for QE 22, QH 21 and also for EQ 21 (a magnesium alloy containing 2% of neodymium component and 1.5% silver) and RR 350 (an aluminium alloy having a high resistance to creep).

Alloy specimens were cast and heat-treated in the same way and subjected to a standard creep test at 300° C. using a stress of 23 N/mm^2. The time to reach 0.2% creep strain was measured and the results are are shown in Table 6, with comparative values for RR 350 and ZT 1 (a magnesium alloy containing zinc and thorium but no rare earth metals which is known to have a high resistance to creep).

The following conclusions may be drawn from these results.

1. Alloys according to the invention containing zirconium as a grain refiner gave room temperature yield stress comparable to those of QE 22 and QH 21 (the specified minimum room temperature yield stress for QE 22 is 175 N/mm^2) and the room temperature ultimate tensile strengths were much higher than for QE 22 and QH 21.

2. The alloys according to the invention gave much better mechanical properties at high temperatures than QE 22 and QH 21, especially at higher yttrium contents. The mechanical properties of QE 22 and QH 21 decline rapidly at temperatures above 250° C. whereas those of the alloys of the invention are maintained to a very considerable degree.

3. Pure yttrium may be replaced by a mixture of yttrium and heavy rare earth metals, containing at least 60% and preferably at least 75% of yttrium giving a large reduction in cost, without loss of mechanical properties.

4. The results for alloys 1–3 show that zirconium may be omitted and good results are still obtained. It is believed that the yttrium itself acts as a grain refiner in the alloy.

5. Especially good tensile properties at both ambient and elevated temperatures are obtained with a content of yttrium component from 2.5 to 7%, neodymium component from 1.5 to 4% and a total of yttrium and neodymium components from 6 to 8.5%.

6. Very good mechanical properties, including creep resistance, at temperatures of 300° C. and above are obtained with a content of yttrium component from 3.5 to 9%, a neodymium component from 2.5 to 5% and total of yttrium and neodymium component from 7.5 to 11.5%, especially when zirconium is absent. However the ductility of these alloys tend to be low.

7. The following range of compositions among the alloys of the invention give a compromise between good ductility and high mechanical properties at room and elevated temperatures which is favourable for many engineering applications: yttrium component 3.5–8%, neodymium component 2–3.5% and total of yttrium and neodymium components 7–10%.

By way of comparison, a known magnesium alloy RZ5 which contains rare earth metals and zinc but no yttrium has much lower tensile properties. For example the specified minimum yield stress for RZ5 at room temperature is 135 N/mm^2 and the alloys of the present invention have considerably higher yield stresses.

Other alloys were cast, heat treated and tested in the same way at 20°, 250°, 300°, 325° and 350° C. and the results are shown in Table 5. Comparative results are given for QE 22, QH 21 and also for EQ 21 (a magnesium alloy containing 2% of neodymium component and 1.5% silver) and RR 350 (an aluminium alloy having a high resistance to creep).

Alloy specimens were cast and heat-treated in the same way and subjected to a standard creep test at 300° C. using a stress of 23 N/mm^2. The time to reach 0.2% creep strain was measured and the results are shown in Table 6, with comparative values for RR 350 and ZT 1

(a magnesium alloy containing zinc and thorium but no rare earth metals which is known to have a high resistance to creep).

In a further series of tests the alloys shown in Table 7 were cast, heat treated in the manner shown in the Table and tested at room temperature. It will be noted that after solution heat treatment and quenching the tensile properties are improved by prolonged ageing at elevated temperature, at least up to 144 hours at 200° C. Also, ageing at elevated temperature of the as-cast alloy without solution heat treatment and quenching gave attractive mechanical properties.

In order to investigate casting behaviour an alloy according to the invention was subjected to a fluidiity spiral casting test and the result is shown in Table 8 with comparative results for QE 22, ZE 63 (a magnesium alloy containing zinc and rare earth metals) and AZ 91 (a magnesium alloy containing magnesium and zinc). The alloy according to the invention gave a favourable result in comparison with the other alloys.

In order to test microporosity on casting an alloy according to the invention was subjected to a standard Spitaler box bottom run casting test in which a sample is cast and radiographed. The result is shown in Table 9 with the result for QE 22 for comparison. Result AA is the area affected by microporosity and MR is the maximum ASTM rating for microporosity in the area affected. The result for the alloy according to the invention is superior to that for QE 22, which itself is an alloy accepted as having good casting behaviour for use in complex aerospace components.

Alloys according to the invention were tested for corrosion by immersion for 28 days in 3% sodium chloride solution saturated with magnesium hydroxide ("immersion" test) and by a Royal Aircraft Establishment test in which they were subjected to salt spray and atmospheric exposure ("RAE" test). The results are shown in Table 10 with corresponding results for alloy QE 22 and RZ5. The RZ5 had been heat treated by simple ageing at elevated temperature, the others had been aged after solution heat treatment and quenching. The results shown in Table 10 record the amount of the alloy corroded away per unit area and unit time, taking RZ5 as unity. It will be seen that the corrosion rate for alloys according to the invention is markedly less than for RZ5 and QE 22.

TABLE 1

ALLOY NO.	DESIGNATION	ANALYSIS % Y	Nd	Zr	Cd	Cu	Ag	HEAT TREATMENT SOLUTION	QUENCH	AGE	TEN. PROPS. (N/mm^2) YS	UTS	E %
1	YED 5,2,½	4.8	2.1	<0.1	0.53	—	—	8 hrs 535° C.	H.W.Q.	20 hrs 200° C.	156	251	3
2	YED 5,2,2	4.8	2.1	"	1.25	—	—	"	"	"	159	231	2
3	YED 5,3,½	5.2	3.3	"	0.41	—	—	8 hrs 525° C.	30% UCON	"	185	248	2
4	YEK 4,2,1	4.3	2.0	0.46	—	—	—	8 hrs 535° C.	H.W.Q.	"	163	308	8
5	YEK 4,4,1	3.7	3.7	0.38	—	—	—	"	"	"	188	302	3
6	YEK 3,5,1	3.2	5.0	0.43	0.02	—	—	"	"	"	193	299	2
7	YEKD 2,4,1,½	1.8	3.9	0.41	0.58	—	—	"	"	"	171	279	3
8	YEKD 4,2,1,½	3.8	1.9	0.38	0.49	—	—	"	"	"	158	282	5
9	YEKD 4,3,1,½	3.9	2.9	0.43	0.55	—	—	"	"	"	181	312	5
10	YEKD 3,4,1,½	3.4	4.0	0.38	0.40	—	—	"	"	"	185	279	1½
11	YEKD 6,3,1,½	5.5	3.5	0.38	0.44	—	—	8 hrs 525° C.	30% UCON	"	215	306	¾
12	YEKC 4,2,1 (0.1)	4.2	2.0	0.40	<0.1	(0.1)	—	16 hrs 475° C.	H.W.Q.	"	179	286	7
13	YEKC 3,4,1 (0.1)	3.4	3.9	0.42	"	(0.1)	—	"	"	"	171	249	1
14	YEKQ 4,3,1,½	4.2	2.6	0.38	"	—	(0.5)	8 hrs 535° C.	"	"	173	328	7
	QE 22	—	2.0	0.6	—	—	2.5	8 hrs 525° C.	"	"	205	266	4
	QH 21	—	1	0.6	—	1 (Thorium)	2.5	"	"	"	210	270	4

TABLE 2

ALLOY NO.	DESIGNATION	ANALYSIS % Y	Nd	Zr	Cd	Cu	Ag	Th	SOLUTION TREATMENT TEMP/TIME	TENSILE PROPERTIES AT 250° C. Y.S. (N/mm^2)	UTS (N/mm^2)	E %
—	QE 22	—	(2)	(0.6)	—	—	(2½)	—	8 hr 525° C.	122	160	30
—	QH 21	—	(1)	(0.6)	—	—	(2½)	(1)	8 hr 525° C.	167	185	16
3	YED 5,3,½	5.2	3.3	<0.1	0.41	—	—	—	8 hr 525° C.	167	266	8
5	YEK 4,4,1	3.7	3.7	0.38	—	—	—	—	8 hr 535° C.	162	265	11
6	YEK 3,5,1	3.2	5.0	0.43	0.02	—	—	—	"	178	266	5
7	YEKD 2,4,1,½	1.8	3.9	0.41	0.58	—	—	—	"	155	230	6
9	YEKD 4,3,1,½	3.9	2.9	0.43	0.55	—	—	—	"	158	256	12
10	YEKD 3,4,1,½	3.4	4.0	0.38	0.40	—	—	—	"	173	265	6½
11	YEKD 6,3,1,½	5.5	3.5	0.38	0.44	—	—	—	"	193	287	2
12	YEKC 4,2,1(0.1)	4.2	2.0	0.40	<0.1	(0.1)	—	—	16 hr 475° C.	142	240	17.5
13	YEKC 3,4,1(0.1)	3.4	3.9	0.42	<0.1	(0.1)	—	—	8 hr 475° C.	144	210	5
14	YEKQ 4,3,1,½	4.2	2.6	0.38	<0.1	—	(0.5)	—	8 hr 535° C.	152	254	17

Analyses in brackets are nominal only.

TABLE 3

ALLOY NO.	DESIGNATION	ANALYSIS % Y	Nd	Zr	Cd	MECHANICAL PROPERTIES AT TEMPERATURE STATED TEMP °C.	Y.S. (N/mm^2)	UTS (N/mm^2)	E %	0.2/100
—	QE 22	2.5% Ag-2.0% Nd-0.6% Zr				20	205	266	4	—
						250	122	160	30	32
						300	70	80	62	—
—	QH 21	2.5% Ag-1% Nd-1% Th-0.6% Zr				20	210	270	4	—

TABLE 3-continued

ALLOY NO.	DESIGNATION	ANALYSIS % Y	Nd	Zr	Cd	MECHANICAL PROPERTIES AT TEMPERATURE STATED TEMP °C.	Y.S. (N/mm²)	UTS (N/mm²)	E %	0.2/100
						250	167	185	16	38
						300	120	131	19	
15	YEKD 931½					20	235	295	½	
		8.1	3.1	0.51	0.6	250	208	320	2	42
						300	176	242	3½	23
						325	161	204	3	—
						350	131	169	8½	—
11	YEKD 631½	5.5	3.5	0.38	0.44	20	215	306	¾	
						250	193	287	2	
						300	176	218	13	
						325	156	182	13	

TABLE 4

ALLOY NO.	DESIGNATION	ANALYSIS % Y	Nd	HRE	Zr	Cd	TENSILE PROP. AT TEMP. STATED Temp °C.	YS (N/mm²)	UTS (N/mm²)	E %
16	YEKD 5,3,1,½(62)	2.8	3.6	1.7	0.47	0.5	20	183	254	1½
							250	154	238	4
10	YEKD 3,4,1,½	3.4	4.0	—	0.38	0.40	20	185	279	1½
							250	173	265	6½
	QE 22	2.5% Ag-.0% Nd-0.6% Zr					20	205	266	4
							250	122	160	30

TABLE 5

DESIGNATION	ANALYSIS % Y	Nd	Zr	Cd	Cu	HRE	HEAT TREATMENT Sol'n	Quench	Age	Tensile Properties (N/mm²) at Temp. Stated 20° C. YS	UTS	E %	250°C. YS	UTS	E %
YE 5½,3	5.5	2.8	—	—	—	—	8 h 525° C.	UCON	20 h 200° C.	194	243	½	153	250	9½
YE 5½,3	5.4	3.0	—	—	—	—	8 h 535° C.	HWQ	"	190	282	1	—	—	—
YED 5,2,½	4.8	2.1	—	0.5	—	—	8 h 535° C.	HWQ	"	156	251	3			
YED 5,3½,½	5.2	3.3	—	0.4	—	—	8 h 525° C.	UCON	"	185	248	2	167	266	8
YED 5½,3,½	5.5	2.9	—	0.5	—	—	"	UCON	"	194	244	¾	154	257	9
YEK 2½,3½,1	2.4	3.6	0.7	—	—	—	8 h 535° C.	UCON	"	153	295	3½	143	243	10
YEK 2½,2,1	2.5	1.8	0.7	—	—	—	"	UCON	"	135	295	9½			
YEK 3,5,1	3.2	5.0	0.4	—	—	—	"	HWQ	"	193	299	2	178	266	5
YEK 3½,3½,1	3.7	3.7	0.4	—	—	—	"	HWQ	"	188	302	3	162	265	11
YEK 4,1½,1	3.8	1.7	0.6	—	—	—	"	UCON	"	154	309	10	121	215	19½
YEK 4,3,1	3.8	2.8	0.6	—	—	—	"	UCON	"	191	330	4	154	252	9
YEK 4,1½,1	3.9	1.7	0.4	—	—	—	8 h 525° C.	UCON	"	159	301	8			
YEK 4½,2,1	4.3	2.0	0.5	—	—	—	8 h 535° C.	HWQ	"	163	308	8			
YEK 5,2,1	5.0	1.8	0.6	—	—	—	8 h 525° C.	UCON	"	180	319	8	152	234	17½
YEK 5½,3,1	5.5	3.0	0.4	—	—	—	8 h 535° C.	HWQ	"	212	335	2	—	—	—
YEK 6½,1½,1	6.3	1.5	0.6	—	—	—	8 h 525° C.	UCON	"	195	303	3	151	234	9½
YEKD 2,4,1,½	1.8	3.9	0.4	0.6	—	—	8 h 535° C.	HWQ	"	171	279	3	155	230	6
YEKD 3½,2,1,½	3.4	1.9	0.6	0.5	—	—	"	UCON	"	159	288	6			
YEKD 3½,4,1,½	3.4	4.0	0.4	0.4	—	—	"	HWQ	"	185	279	1½	173	265	6½
YEKD 4,2,1,½	3.8	1.9	0.4	0.5	—	—	"	HWQ	"	158	282	5			
YEKD 4,3,1,½	3.9	2.9	0.4	0.6	—	—	"	HWQ	"	181	312	5	158	256	12
YEKD 5½,3½,1,½	5.5	3.5	0.4	0.4	—	—	"	UCON	"	215	306	¾	193	287	2
YEKD 6,1½,1,½	6.0	1.5	0.6	0.5	—	—	8 h 525° C.	UCON	"	188	322	5	151	236	6
YEKD 8,3,1,½	8.1	3.1	0.6	0.5	—	—	"	UCON	"	235	295	½	208	320	2
YEKC 3½,4,1,0	3.4	3.9	0.4	—	(0.1)	—	16 h 475° C.	HWQ	"	171	249	1	144	210	5
YEKC 4,2,1,0	4.2	2.0	0.4	—	(0.1)	—	"	HWQ	"	179	286	7	142	240	17.5
YEKC 4½,3,1,0	4.6	2.9	0.5	—	(0.1)	—	8 h 500° C.	UCON	"	202	317	3½	158	239	4
Y(62) K 8,1	5.0	—	0.5	—	—	3.0	8 h 525° C.	UCON	"	165	260	2	136	216	14
Y(62) EK 2½,2,1	1.6	1.9	0.6	—	—	(1.0)	8 h 535° C.	UCON	"	139	269	5			
Y(62) EK 3½,2,1	2.2	1.9	0.5	—	—	(1.4)	8 h 525° C.	UCON	"	159	291	6			
Y(62) EK 3½,2,1	2.2	1.9	0.5	—	—	(1.4)	"	UCON	"	156	257	3			
Y(62) EK 4½,2,1	2.7	1.9	0.6	—	—	(1.7)	"	UCON	"	169	289	3	131	209	5
Y(62) EKD 3½,2,1,½	2.1	1.9	0.6	0.4	—	(1.3)	8 h 535° C.	UCON	"	162	272	3½	130	218	12
Y(62) EKD 4½,3½,1,½	2.8	3.6	0.5	0.5	—	(1.7)	8 h 525° C.	UCON	"	183	254	1½	154	238	4
QE 22										205	266	4	122	160	30
QH 21										210	270	4	167	185	16
EQ 21										195	260	4	152	166	15
RR350										233	258	1	144	185	3

DESIGNATION	Tensile Properties (N/mm²) at Temp. Stated 300° C. YS	UTS	E %	325° C. YS	UTS	E %	350° C. YS	UTS	E %
YE 5½,3	139	200	7						
YE 5½,3	—	—	—						
YED 5,2,½									
YED 5,3½,½									

TABLE 5-continued

YED 5½,3,½	152	196	6½						
YEK 2½,3½,1	130	168	8						
YEK 2½,2,1									
YEK 3,5,1									
YEK 3½,3½,1									
YEK 4,1½,1	92	175	17						
YEK 4,3,1	126	174	11½						
YEK 4,1½,1									
YEK 4½,2,1									
YEK 5,2,1	99	182	20						
YEK 5½,3,1	—	—	—						
YEK 6½,1½,1	104	180	13						
YEKD 2,4,1,½									
YEKD 3½,2,1,½	102	165	16						
YEKD 3½,4,1,½									
YEKD 4,2,1,½									
YEKD 4,3,1,½									
YEKD 5½,3½,1,½	176	218	13	156	182	13			
YEKD 6,1½,1,½	105	184	15						
YEKD 8,3,1,½	176	242	3½	161	204	3	131	159	8½
YEKC 3½,4,1,0									
YEKC 4,2,1,0									
YEKC 4½,3,1,0	117	188	7½						
Y(62) K 8,1	109	180	11						
Y(62) EK 2½,2,1									
Y(62) EK 3½,2,1									
Y(62) EK 3½,2,1									
Y(62) EK 4½,2,1	106	163	8						
Y(62) EKD 3½,2,1,½	113	161	12						
Y(62) EKD 4½,3½,1,½									
QE 22	70	80	62						
QH 21	120	131	19						
EQ 21	115	128	10						
RR350	113	151	4½				83	114	6½

TABLE 6

DESIGNATION	ANALYSIS % Y	Nd	Zr	Cd	HRE	TIME TO 0.2% CREEP STRAIN (HRS)(1)
YE 3½,5	3.7	5.0	—	—	—	954
YE 5½,3	5.5	2.8	—	—	—	1850
YEK 3½,5,1	3.7	5.0	0.5	—	—	27
YEK 4,1½,1	3.8	1.7	0.6	—	—	204
YEK 4,3,1	3.8	2.8	0.6	—	—	155
YEK 5,2,1	5.0	1.8	0.6	—	—	170
YEK 6½,1½,1	6.3	1.5	0.6	—	—	59
YEK 6½,3,1	6.4	3.0	0.5	—	—	152
YEKD 3½,4,1,½	3.4	4.0	0.4	0.4	—	44
YEKD 6,1½,1,½	6.0	1.5	0.6	0.5	—	17
YEKD 8,3,1,½	8.1	3.1	0.6	0.5	—	120
Y (62) K 8,1	5.0	—	0.5	—	(3.0)	124
Y (62) EK 4½,2,1	2.7	1.9	0.6	—	(1.7)	78
Y (75) EK 8½,2½,1	6.5	2.4	0.5	—	(2.2)	132
Y (62) EKD 3½,2,1,½	2.1	1.9	0.6	0.4	(1.3)	79
ZT1	M.E.L.DATA (typical)					100
RR350	R.R.DATA (typical)					3000

TABLE 8

ALLOY	SPIRAL LENGTH (cm) AT 780° C.
ZE63	80
AZ91	100
QE 22	69
YEK 5½,3,1	94

TABLE 9

ALLOY	PLATE D[1] AA[2]	MR[3]	PLATE E AA	MR	PLATE F AA	MR
QE 22	50	7	80	4	50	7
YEK 5½,3,1	50	5	20	2	50	6

TABLE 10

ALLOY	AVERAGE CORROSION RATE IMMERSION	RAE TEST
YEK 5,1,1	0.6	0.7
YEK 5½,1½,1	0.6	0.7
RZ5	1	1
QE 22	2.6	9

TABLE 7

DESIGNATION	Analysis % Y	Nd	Zr	Type of Test Bar	Heat Treatment Solution	Quench	Age	R.T. Tensile Properties (N/mm²) Y.S.	U.T.S.
YEK 5½,3,1	5.3	3.2	0.45	HF	8 h 517° C.	H.W.Q.	20 h 200° C.	200	315
					"	"	35 h 200° C.	205	310
					"	"	144 h 200° C.	232	312
				DTD	8 h 517° C.	H.W.Q.	20 h 200° C.	216	298
					"	"	144 h 200° C.	229	293
YEK 5½,3,1	5.68	2.92	0.56	HF	AS CAST		—	146	230
					AS CAST		20 h 200° C.	174	262
					8 h 535° C.	H.W.Q.	20 h 200° C.	208	340
				DTD	AS CAST		20 h 200° C.	191	236
					8 h 535° C.	H.W.Q.	20 h 200° C.	209	316

We claim:

1. A magnesium alloy consisting of, apart from normal impurities,

(a) from 1.5 to 10% by weight of an yttrium component consisting of at least 60% by weight of yttrium and the balance, if any, of heavy rare earth metals, and

(b) from 1 to 6% by weight of a neodymium component consisting of at least 60% by weight of neodymium, not more than 25% by weight of lanthanum and substantially all the balance, if any, of praseodymium,

the remainder of the alloy consisting of magnesium.

2. An alloy according to claim 1, in which the total content of yttrium component and neodymium component is from 4 to 14%.

3. An alloy according to claim 1, which contains from 2.5 to 7% of yttrium component and 1.5 to 4% of neodymium component, the total content of yttrium component and neodymium component being from 6 to 8.5%.

4. An alloy according to claim 1, which contains from 3.5 to 9% of yttrium component and from 2.5 to 5% of neodymium component, the total content of yttrium and neodymium components being from 7.5 to 11.5%.

5. An alloy according to claim 1, which contains from 3.5 to 8% of yttrium component and from 2 to 3.5% neodymium component, the total content of yttrium component and neodymium component being from 7 to 10%.

6. An alloy according to claim 1, in which the yttrium component contains at least 75% by weight of yttrium.

7. An alloy according to claim 1, which also contains up to 1% by weight of zirconium.

8. An alloy according to claim 1, which also contains up to 1% by weight of cadmium.

9. An alloy according to claim 1, which also contains up to 0.15% by weight of copper or up to 1% by weight of silver.

10. An alloy according to claim 1, which further contains one or more of the following constituents by weight:

Thorium—0–1%
Lithium—0–6%
Gallium—0–2%
Indium—0–2%
Thallium—0–5%
Lead—0–1%
Bismuth—0–1%
Manganese—0–2%.

11. An alloy according to claim 1, containing from 1.5 to 9% of the yttrium component and in which the yttrium component contains at least 62% of yttrium.

12. An article obtained by casting a magnesium alloy according to claim 1.

13. An article according to claim 12, in which the article has been subjected to solution heat treatment, quenching and ageing at an elevated temperature.

14. An article according to claim 13, in which the solution heat treatment is carried out at a temperature of about 20° C. below the solidus temperature for about 8 hours, quenching is carried out in water or a solution of a quench moderating agent and ageing is carried out at a temperature of about 200° C.

15. An article according to claim 13 or 14, in which the article is aged for about 20 hours.

16. An article according to claim 13 or 14, in which the article is aged for up to 144 hours.

17. An article according to claim 13, which has been aged at an elevated temperature without solution heat treatment or quenching.

* * * * *

US006676697B1

(12) **United States Patent**
Richter

(10) **Patent No.: US 6,676,697 B1**
(45) **Date of Patent: Jan. 13, 2004**

(54) **STENT WITH VARIABLE FEATURES TO OPTIMIZE SUPPORT AND METHOD OF MAKING SUCH STENT**

(75) Inventor: **Jacob Richter**, Tel Aviv (IL)

(73) Assignee: **Medinol Ltd.**, Tel Aviv (IL)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/040,145**

(22) Filed: **Mar. 17, 1998**

Related U.S. Application Data

(62) Division of application No. 08/716,039, filed on Sep. 16, 1996, now Pat. No. 5,807,404.

(51) **Int. Cl.**[7] **A61F 2/06**
(52) **U.S. Cl.** **623/1.16**; 623/23.7
(58) **Field of Search** 623/1, 11, 12, 623/1.15, 1.16, 23.7; 606/108, 191, 194, 195, 198

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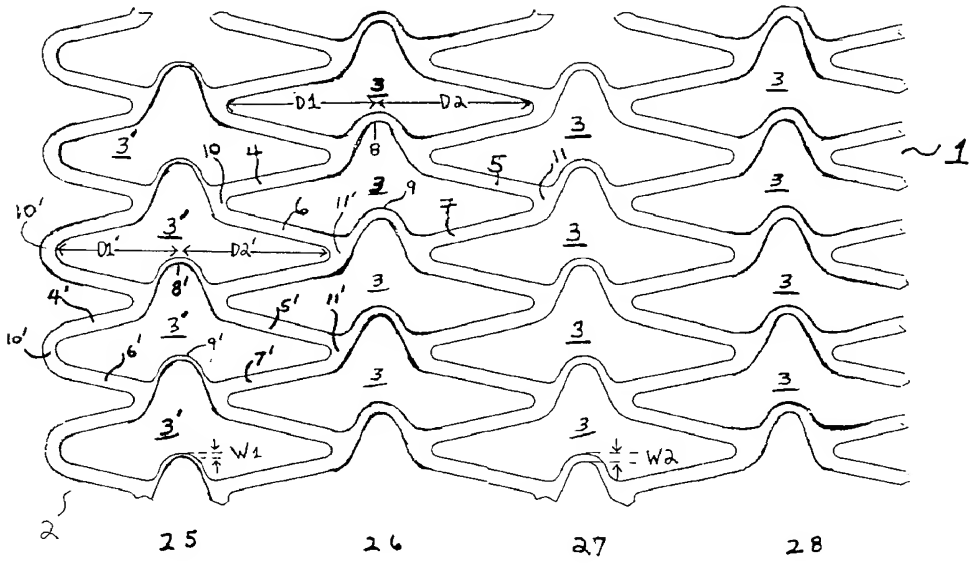
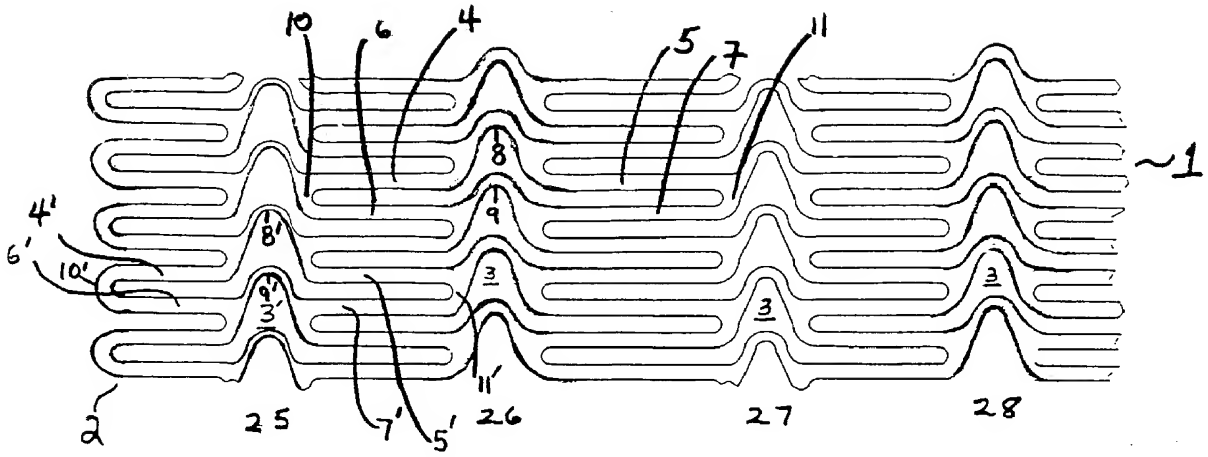
Primary Examiner—Paul B. Prebilic
(74) *Attorney, Agent, or Firm*—Kenyon & Kenyon

(57) **ABSTRACT**

An intravascular stent especially suited for implanting in curved arterial portions or ostial regions. The stent can include an end region which is fabricated to have a greater radial strength than the remaining axial length of the stent. Such a stent is particularly suited for use in ostial regions, which require greater support near the end of the stent. The stent alternatively can include sections adjacent the end of the stent with greater bending flexibility than the remaining axial length of the stent. Such a stent is particularly suited for use in curved arteries. The stent can also be constructed with an end that has greater radial strength and sections adjacent the end with greater bending flexibility. Such a stent prevents flaring of the stent end during insertion.

4 Claims, 7 Drawing Sheets

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6
4
5
7
11
8
9
1
4'
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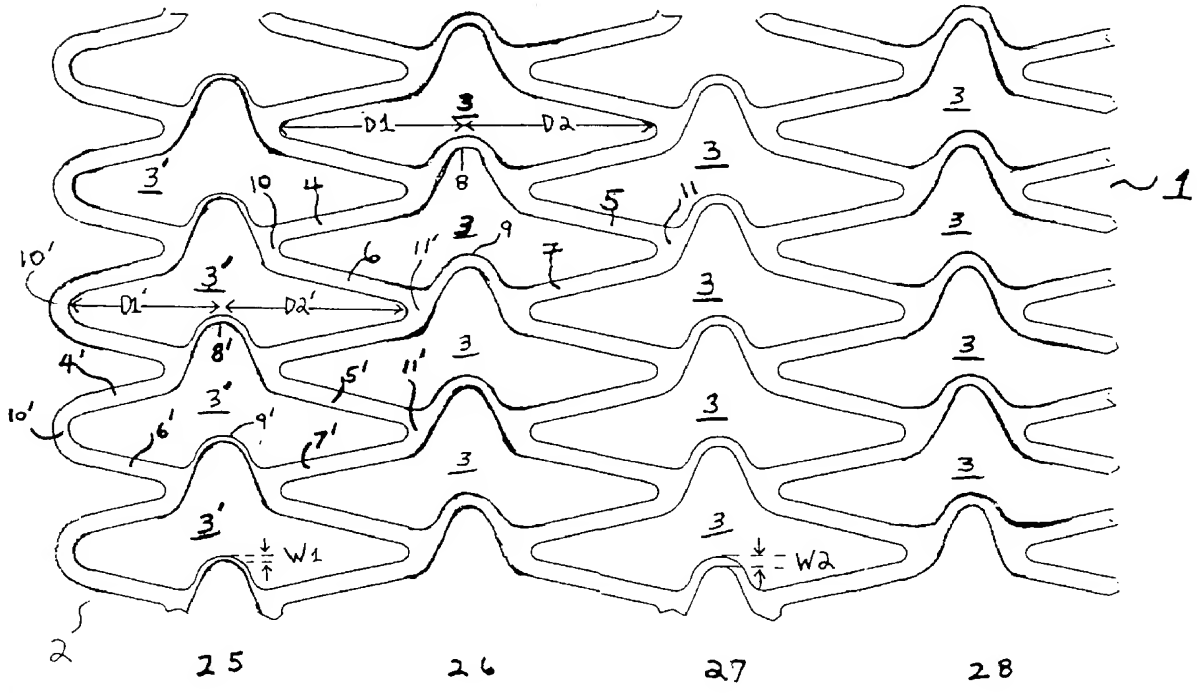
10'
8'
9'
3'
3
11'
2
25
7'
5'
26
27
28

FIG. 1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D1'
D2'
W1
W2
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2
25
26
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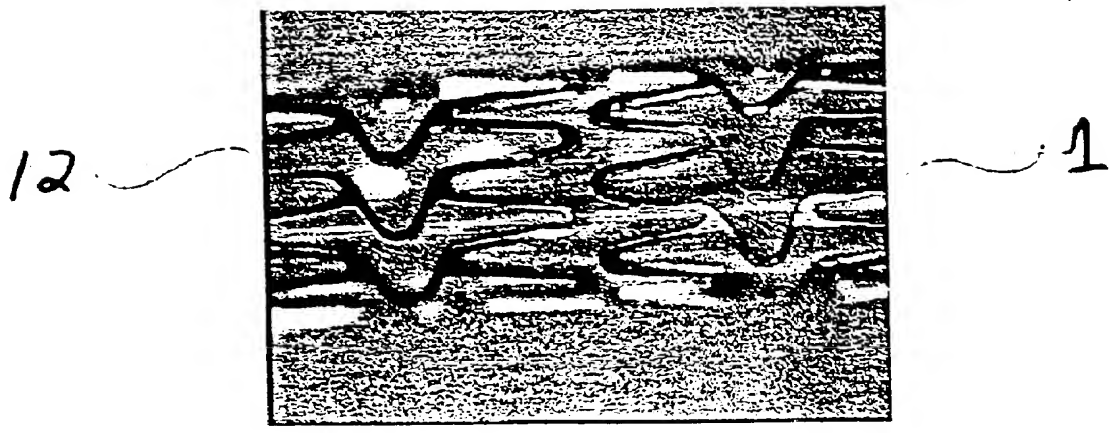
FIG. 2



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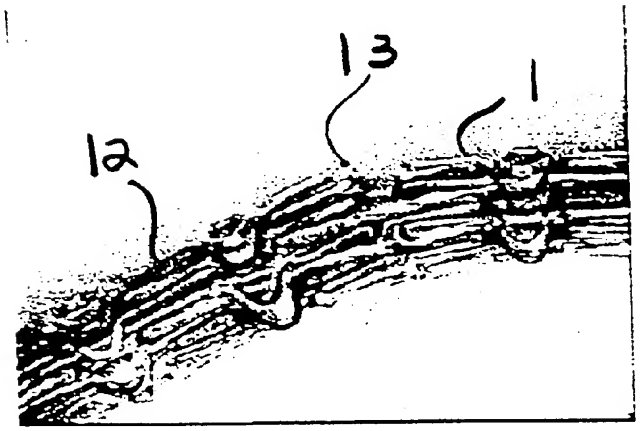

FIG. 4

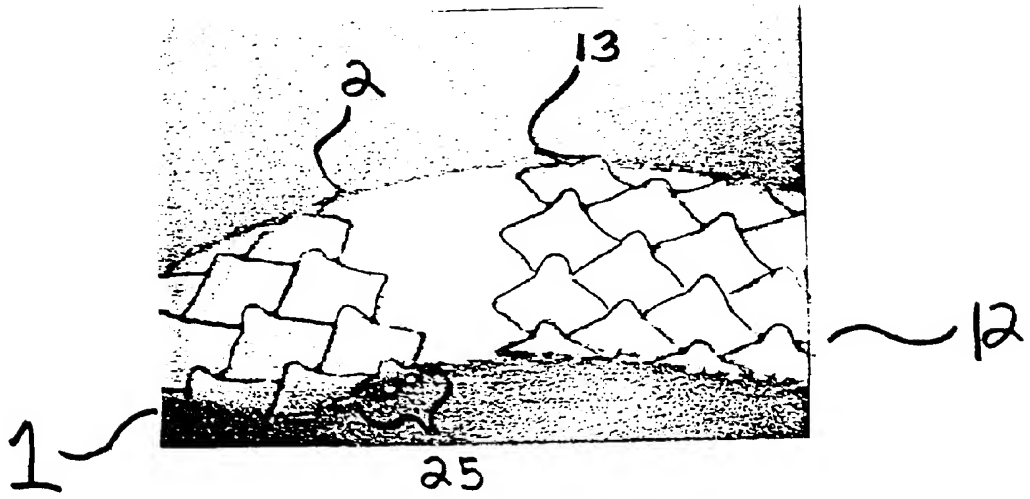

FIG. 5

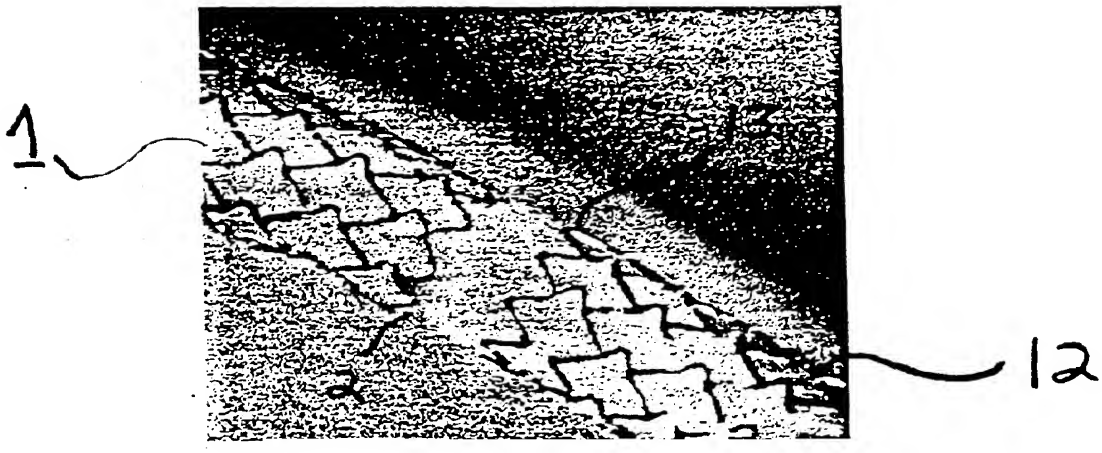

FIG. 6

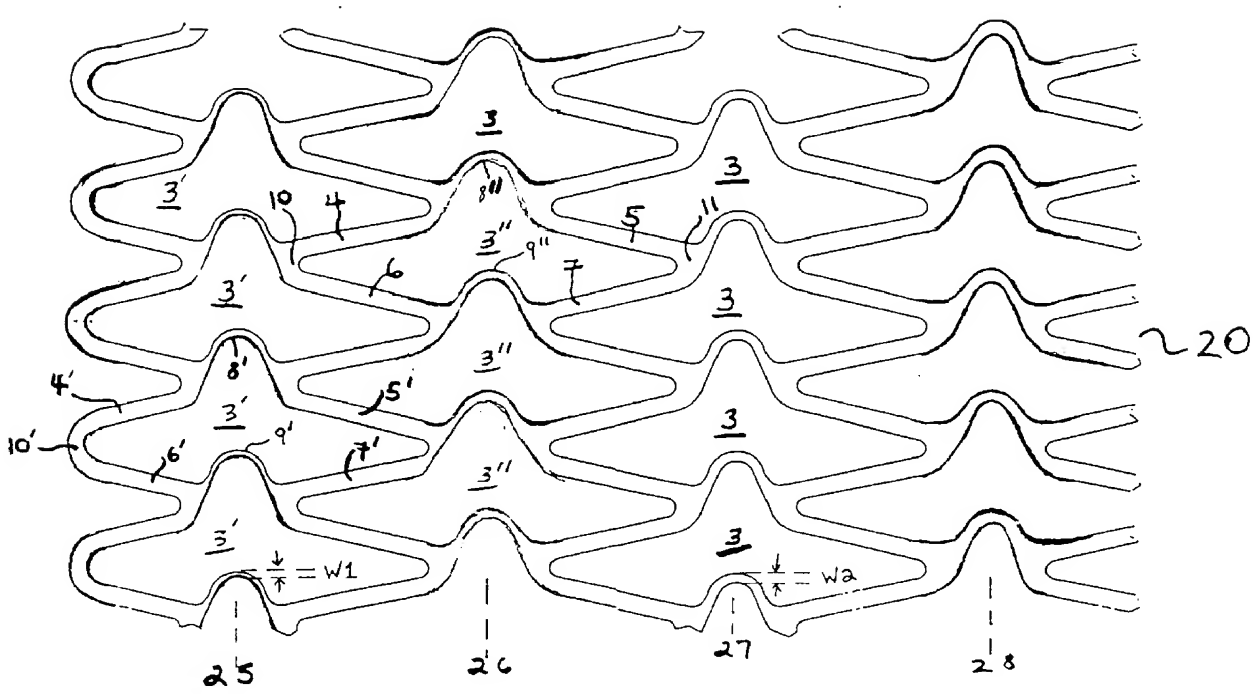

FIG. 7

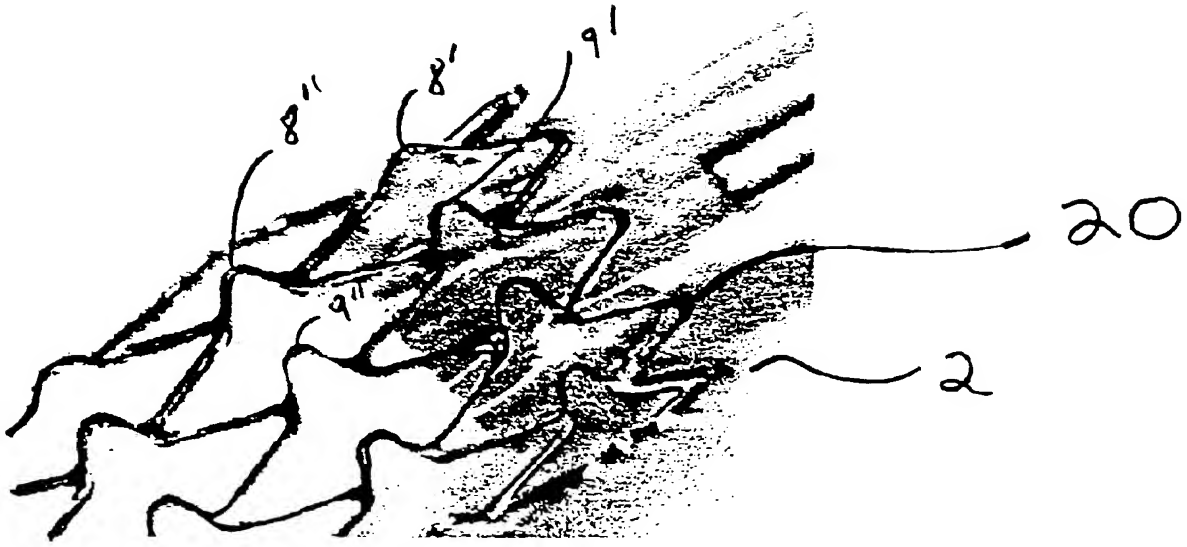

FIG. 8

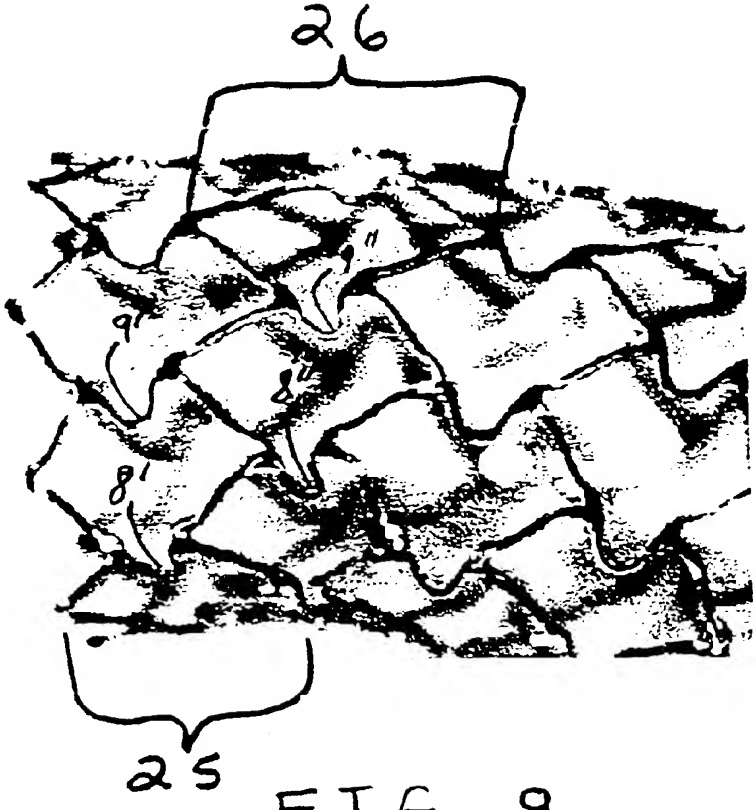

FIG. 9

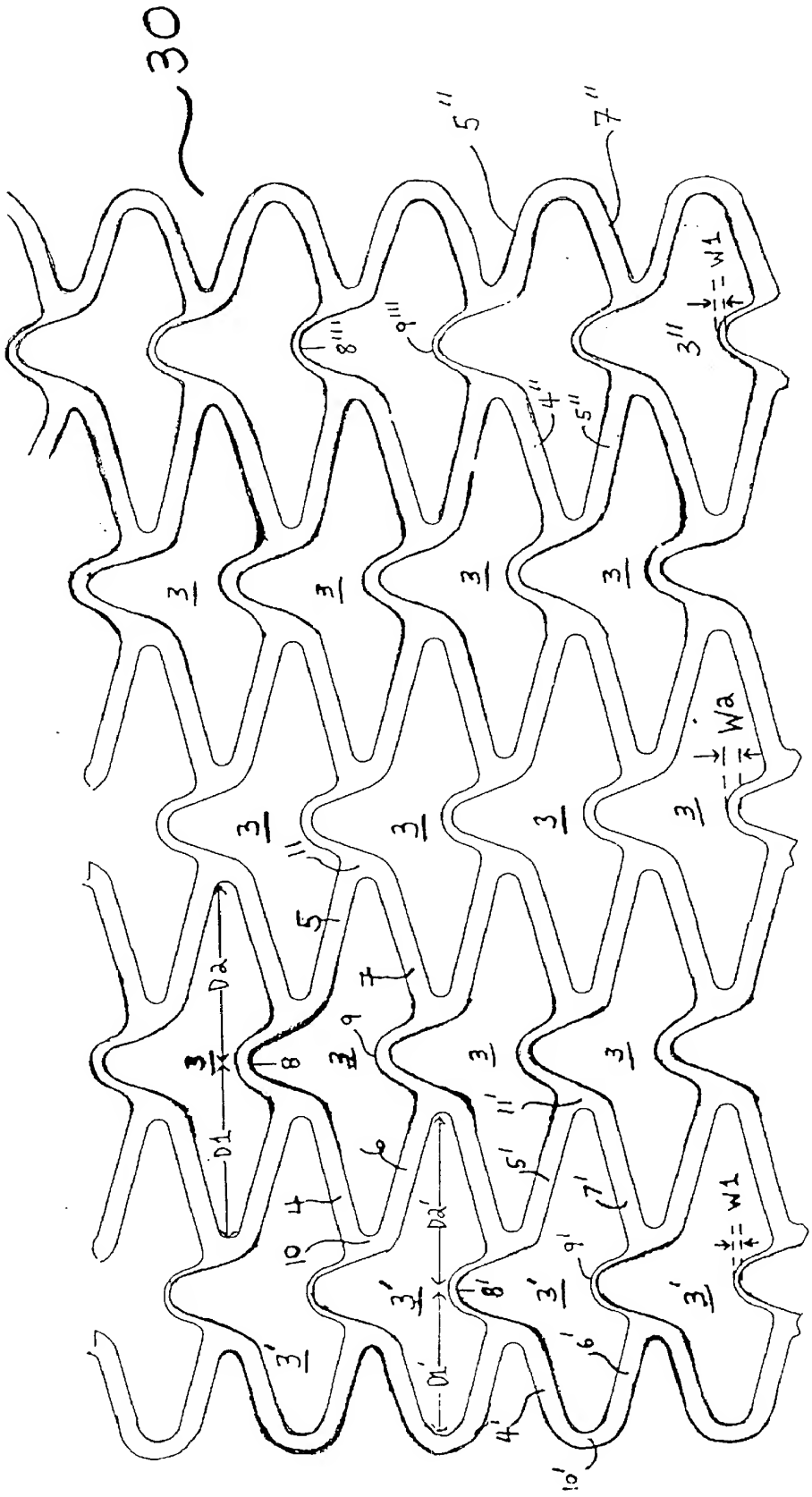
30
5''
7''
8'''
9'''
4''
5''
3''
W1
3
11
5
7
9
8
Da
D1
10
4
6
3'
11'
5'
7'
9'
8'
Da'
D1'
4'
6'
10'
W1
Wa
25
26
27
28
29

FIG. 10

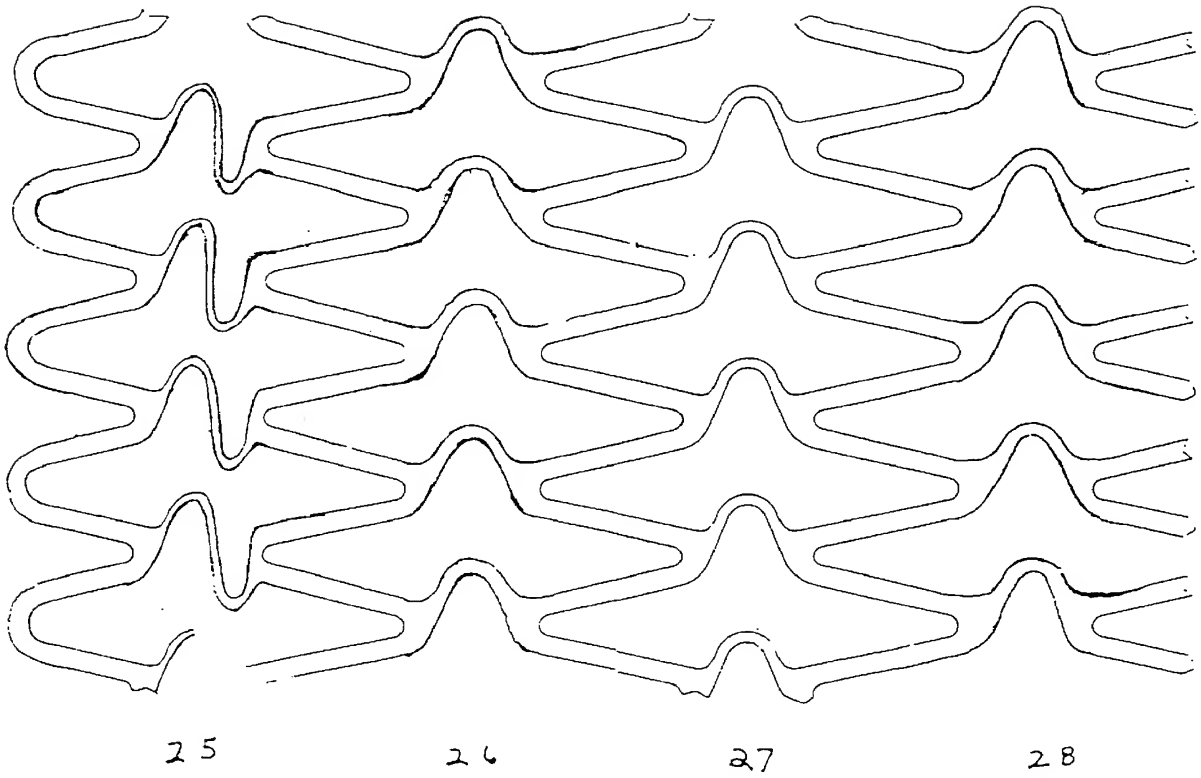

FIG. 11

STENT WITH VARIABLE FEATURES TO OPTIMIZE SUPPORT AND METHOD OF MAKING SUCH STENT

This application is a division of Ser. No. 08/716,039 filed on Sep. 16, 1996, now U.S. Pat. No. 5,807,404.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to stents for implanting into a living body. In particular, the present invention relates to intraluminal stents especially suited for implanting in a variety of lumens having variable characteristics, such as variable curvature, side branching, variable diameter, variable wall compliance or "end effects" of either the lumen, as found, e.g., in ostia, or the stent as the parameters may change at its ends.

2. Description of the Prior Art

It is well known to use a stent to expand and impart support to different bodily conduits, such as blood vessels, by expanding a tube-like structure inside the vessel requiring support against collapse or closure. U.S. Pat. No. 5,449,373 shows a stent preferably used for vascular implantation as part of a balloon angioplasty procedure. The stent of U.S. Pat. No. 5,449,373 may be delivered through, or implanted in, a curved vessel. One shortcoming of conventional stents is that they may have deficiencies due to "end effects" where the ends of the stent tend to "flare out" during insertion or after expansion or have a decreased radial force at the end. Still another shortcoming of conventional stents is they do not have different characteristics, (e.g., flexibility and rigidity), to accommodate any changing characteristics of the section of the lumen requiring different stent characteristics.

SUMMARY AND OBJECTS OF THE INVENTION

The present invention provides for various embodiments of an intraluminal stent which includes varied or different mechanical properties along the axial length of the stent in order to improve stent end effects, or to accommodate variable vessel features. As a result, the various embodiments of the present invention allow for variable properties such as flexibility or radial support between axial regions of the stent. These varied properties can be accomplished in a number of different ways, including decreasing or increasing the thickness or width of elements of one or more of the sections relative to other sections and/or increasing or decreasing the axial length of one or more of the sections and/or changing the cell shape and size and/or changing material properties (e.g., strength, elasticity, etc.) of the material in one section relative to other sections.

The various embodiments of the stents of the present invention may be adapted to provide more flexibility at the ends to allow the stent to accommodate the curvature of a vessel in which the stent is implanted. The degree of flexibility and the distance from the end of the stent to which the extra flexibility is imparted may be varied as specific applications dictate. This flexibility at the ends reduces the chance of a potential trauma point being created in the vessel by the stent tip pressing on the wall outside of the curve if the stent is not flexible enough along its longitudinal axis. In one embodiment of the present invention, flexibility of the stent ends is increased by reducing the gauge of the material used in a section or sections at the stent ends. In another embodiment the flexibility of the stent ends is increased by changing the dimensions of a section or sections at the stent ends. In yet another embodiment of the invention, the flexibility of the stent ends is increased by changing both the dimensions and the gauge of the material used in a section or sections at the stent ends.

The various embodiments of the stents of the present invention may also be adapted to insure increased radial strength at the ends. Radial strength is the resistance of a section of the stent, in an expanded state, to radial contraction. Increasing the radial strength of a stent at the ends is particularly advantageous for stents supporting ostia. Because lesions at an ostium tend to be more calcified or hardened, and therefore require more support, the section of the stent supporting the ostium must be relatively strong. It is also the case that a stent with uniform characteristics has a decreased radial force at the end due to the "end effect" whereby the last row has no support on one side. In one embodiment of the present invention, the strength of the stent at the end supporting, e.g., the ostium, is increased by reducing the length of some sections at the stent end.

The various embodiments of the stent of the present invention also reduce the chance of "flare" at the end of the stent while the stent is being fed into a vessel. During insertion of the catheter delivery system into a curved vessel, the delivery system, including the stent crimped on it, bend along the curvature of the vessel. This bending of the stent can cause a "flaring out" of the leading edge of the stent. This flaring could cause the stent to catch on the surface of the vessel which could result in trauma to the vessel, could inhibit further insertion and proper positioning in the target area, and could cause plaque to break off, which could embolize and clog the vessel. In one embodiment of the present invention, flare is minimized by making the section at the stent end stronger by reducing its length, and by making sections adjacent to the stent end more flexible by reducing their widths, thus, decreasing the bending strength of those sections. Bending strength is the resistance of a section of the stent to axial bending. As a result, the end of the stent remains tightly crimped on the balloon, and the bending moment is taken up by the deformation of the more flexible sections. Upon expansion, the reduced bending strength allows the end of the stent to curve and fit better the curvature of the vessel, thereby, reducing the pressure of the tip of the stent on the internal wall of the vessel being treated.

It is an object of this invention to provide a stent which does not have sharp points or protrusions at its end concentrating pressure on the vessel's wall upon expansion of the stent in a curved portion of a vessel.

It is another object of this invention to provide a stent having a radial force at its distal end that is greater than the radial force in the portion of the stent proximal to the distal end.

It is yet another object of this invention to provide an expandable stent, comprising: a plurality of interconnected flexible cells defining a stent having a proximal end and a distal end and a longitudinal axis, the cells arranged in a plurality of interconnected flexible rows disposed along the longitudinal axis of the stent with a distal row disposed at the distal end of the stent and a proximal row disposed at the proximal end of the stent, wherein the cells disposed in the distal row of the stent are adapted to exert greater radial force and are further adapted to be more flexible than the cells disposed in the rows disposed between the distal row and the proximal end of the stent.

It is still another object of this invention to provide an expandable stent, comprising: a plurality of interconnected

flexible cells defining a stent having a proximal end and a distal end and a longitudinal axis, the cells arranged in a plurality of interconnected flexible rows disposed along the longitudinal axis of the stent with a distal row disposed at the distal end of said stent and a proximal row disposed at the proximal end of the stent, wherein the cells in the distal row of the stent and the cells disposed in the proximal row of the stent are adapted to exert greater radial force and are further adapted to be more flexible than the cells disposed in the rows disposed between the distal row and the proximal row.

It is another object of this invention to provide an expandable stent, comprising: a) a plurality of interconnected flexible cells defining a stent having a proximal end and a distal end and a longitudinal axis, the cells arranged in a plurality of interconnected flexible rows disposed along the longitudinal axis of the stent with a distal row disposed at the distal end of the stent and a proximal row disposed at the proximal end of the stent, each of the flexible cells comprising a first member, a second member, a third member, and a fourth member; b) a first C-shaped loop disposed between the first member and the third member; c) a second C-shaped loop disposed between the second member and the fourth member; d) a first flexible connector disposed between the first member and the second member; and e) a second flexible connector disposed between the third member and the fourth member, wherein the cells of the distal row are provided with first and third members that are shorter than the second and fourth members in the distal row, and wherein the distal row is provided with first and second flexible connectors that are more flexible than the flexible connectors in the cells in the other rows of the stent.

It is yet another object of this invention to provide an expandable stent, comprising: a) a plurality of interconnected flexible cells defining a longitudinal stent having a proximal end and a distal end and a longitudinal axis, the cells arranged in a plurality of interconnected flexible rows disposed along the longitudinal axis of the stent with a distal row disposed at the distal end of the stent and a proximal row disposed at the proximal end of the stent, each of the flexible cells comprising a first member, a second member, a third member, and a fourth member; b) a first C-shaped loop disposed between the first member and the third member; c) a second C-shaped loop disposed between the second member and the fourth member; d) a first flexible connector disposed between the first member and the second member; and e) a second flexible connector disposed between the third member and the fourth member, wherein the cells of the distal row are provided with first and third members that are shorter than the second and fourth members in the distal row, and wherein the distal row, and the row proximal to the distal row, are provided with first and second flexible connectors that are more flexible than the flexible connectors in the other rows of the stent.

It is a further aspect of this invention to provide an expandable stent comprising: a) a plurality of flexible cells defining a stent having a proximal end and a distal end and a longitudinal axis, the cells arranged in a plurality of flexible rows along the longitudinal axis with a distal row disposed at the distal end of the stent and a proximal row disposed at the proximal end of the stent, each of the flexible cells comprising a first member, a second member, a third member, and a fourth member; b) a first C-shaped loop disposed between the first member and the third member; c) a second C-shaped loop disposed between the second member and the fourth member; d) a first flexible connector disposed between the first member and the second member; and e) a second flexible connector disposed between the third member and the fourth member, wherein the cells of the distal row are provided with first and third members that are shorter than the second and fourth members in the distal row, and wherein the cells of the proximal row are provided with second and fourth members that are shorter than the first and third members in the proximal row, and wherein the distal row, and the row proximal to the distal row, and the proximal row and the row distal to the proximal row are provided with first and second flexible connectors that are more flexible than the flexible connectors in the other rows of the stent.

It is yet another object of this invention to provide an expandable stent, comprising: a plurality of flexible cells defining a stent having a proximal end and a distal end, the stent provided with means for imparting a radial force at its distal end that is greater than the radial force in the portion of the stent proximal to the distal end.

It is yet a further object of this invention to provide an expandable stent, comprising: a plurality of flexible cells defining a stent having a proximal end and a distal end, the stent provided with means for imparting a radial force at its proximal and distal ends that is greater than the radial force of that portion of the stent disposed between the proximal and distal ends.

It is another object of this invention to provide an expandable stent for treating a lumen having a unique characteristic along a portion of the lumen, comprising: a plurality of interconnected flexible cells, the cells arranged in a plurality of interconnected flexible rows defining a stent having a proximal end and a distal end and a longitudinal axis, wherein at least one of the rows is adapted to accommodate the unique characteristic of that portion of the lumen in contact with the adapted row or rows.

It is yet another object of this invention to provide a single flexible stent with a unibody or one-piece construction which is capable of imparting support to a lumen or vessel along the entire length of the stent and in which portions of the stent are adapted or modified so as to have characteristics, e.g., bending strength or radial strength, that are different than the characteristics or features in the rest of the stent along it's longitudinal axis or about its circumference. The change in stent features will either accommodate non-uniformity in the treated lumen or may create different environmental conditions in different areas in the lumen. Non-uniformity in a treated vessel can be of many different types such as an ostium, change in diameter, change in curvature, non-continuous cross-section such as triangular or square, or non-uniformity in surface nature, etc. To accommodate such non-uniformity, portions of the stent may be adapted to provide changing dimension, flexibility, rigidity, size of cells, shape of cells, and response to pressure as dictated by specific applications. Specific applications may dictate, e.g., a desired higher radial force at one end while the other portions of the stent provide a substantially continuous support to the vessel wall with the gaps in the stent sized small enough to reduce the likelihood of tissue prolapse. Other applications may dictate a desired degree of stiffness in the center to reduce the likelihood of breakage and impart the desired degree of softness at the end to allow for the best fit with the anatomy of the target area. Other applications may dictate that one or more of the rows be provided with cells that are sized larger than the cells in the remaining rows of the stent so as to provide access to a side branch in the lumen, e.g., for introducing a second stent through one of the larger sized cells so as to permit construction of a bifurcated stent within the lumen. Still another application may dictate that one or more of the rows be

provided with cells which are adapted or modified so that upon expansion of the stent the portion of the stent defined by the adapted or modified row or rows has a diameter that is either larger or smaller than the remaining portions of the stent to accommodate lumens with non-uniform diameters. One or more rows of cells may also be adapted or modified so as to have varying radial force, or varying longitudinal flexibility, or to correct for a change in properties at the end of the stent.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** shows an illustration of the basic pattern of an embodiment of the stent of the present invention, shown in an unexpanded state;

FIG. **2** shows an illustration of the pattern of the stent of FIG. **1**, in a partially expanded state;

FIG. **3** is a side view showing a conventional stent and a stent manufactured in accordance with one embodiment of the invention;

FIG. **4** shows the stents of FIG. **3** crimped on a balloon catheter and bent prior to expansion;

FIG. **5** shows the stents of FIG. **4** after they have been expanded in a curve;

FIG. **6** shows the stents of FIG. **3** partially expanded on a substantially straight balloon catheter;

FIG. **7** shows an alternative embodiment of the invention provided with a shortened C-shaped loop and in which two rows of cells are provided with thinner gauge U-shaped loops;

FIG. **8** shows the stent of FIG. **7** partially expanded on a substantially straight balloon catheter;

FIG. **9** shows the stent of FIG. **7** after it has been expanded on a curved catheter as it would be when inserted around a bend in a vessel;

FIG. **10** shows an alternative embodiment of a stent constructed in accordance with the invention; and

FIG. **11** shows the "S" or "Z" shaped loops constructed in accordance with the invention.

DETAILED DESCRIPTION OF THE INVENTION

FIG. **1** shows the general configuration of one embodiment of a stent **1** fabricated in accordance with the present invention. The stent **1** may be fabricated of bio-compatible materials such as stainless steel **316**L, gold, tantalum, nitinol or other materials well known to those skilled in the art as suitable for this purpose. The dimensions and gauge of material utilized may be varied as specific applications dictate. The stents of the present invention generally may be constructed in a manner in accordance with the stent described in U.S. patent application Ser. No. 08/457,354, filed Jun. 1, 1995, the disclosure of which is incorporated herein by reference.

FIG. **1** is a side view of the distal end **2** of stent **1** of the present invention, showing the general pattern of the stent. As shown in FIGS. **1** and **2** the pattern may be described as a plurality of cells **3** and **3'**. Each cell **3** is provided with a first member **4**, a second member **5**, a third member **6**, and a fourth member **7**. A first C-shaped loop **10** is disposed between the first member **4** and the third member **6** and a second C-shaped loop **11** is disposed between the second member **5** and the fourth member **7**. In each of the cells **3**, first member **4**, second member **5**, third member **6**, and fourth member **7** are substantially equal. Thus, first C-shaped loop **10** is displaced a distance D1 and second C-shaped loop **11** is displaced a distance D2 from the center of cell **3**. In a preferred embodiment, D1 is substantially equal to D2. A first flexible connector **8** is disposed between the first member **4** and the second member **5** and a second flexible connector **9** is disposed between third member **6** and fourth member **7**. The flexible connectors **8** and **9** may be made in a variety of shapes, e.g., an "S" or a "Z" shape as shown in FIG. **11**. In a preferred embodiment, a "U" shape is utilized as shown in FIGS. **1** to **10**.

FIG. **1** shows the pattern of stent **1** in an unexpanded state, i.e., that state in which the stent **1** is first inserted in a particular vessel in which a balloon angioplasty procedure is to be performed, but before balloon inflation. FIG. **2** shows the pattern of stent **1** in a partially expanded state, i.e., that state after the balloon has been expanded, e.g. by a balloon, and the state in which the stent **1** remains in the vessel which it supports. The plurality of interconnected cells **3** and **3'** form a plurality of interconnected rows **25**, **26**, **27**, and **28** of cells disposed along the longitudinal axis of the stent **1**. FIGS. **1** and **2** show a distal row **25** disposed at the distal end **2**, a row **26** adjacent to and proximal to distal row **25**, a row **27** adjacent to and proximal to row **26**, and a row **28** adjacent to and proximal to row **27**. It will be appreciated that the number of rows, and the number of cells per row, and the shape of each cell, may be varied as specific applications require.

As shown in FIGS. **1** and **2**, the cells **3'** in distal row **25** differ from the cells **3** in rows **26**, **27**, and **28**. The first member **4'** and the third member **6'** of the cells **3'** in row **25** are shorter than the first member **4** and the third member **6** of the cells **3** in rows **26**, **27** and **28**. In cell **3'**, first member **4'** is substantially equal to third member **6'**, however, first member **4'** and third member **6'** are shorter than second member **5'** and fourth member **7'**. The shorter members **4'** and **6'** result in a first C-shaped loop **10'** that is not disposed as far away from the center of the cell **3'** as second C-shaped loop **11'**. Thus, first C-shaped loop **10'** may be thought of as being "shorter" than second C-shaped loop **11'**. As shown in FIG. **2**, first C-shaped loop **10'** is disposed a distance D1' that is less than the distance D2' that second C-shaped loop **11'** is disposed from the center of the cell **3'**. In an especially preferred embodiment, D1' is about 15% less than D2'.

FIGS. **1** and **2** also show that the distal row **25** of the stent **1** is provided with a first U-shaped loop **8'** and a second U-shaped loop **9'** that are more flexible than the first U-shaped loop **8** and second U-shaped loop **9** of cells **3** in rows **26**, **27**, and **28** of the stent **1**. This greater flexibility in the U-shaped loops **8'** and **9'** may be accomplished in a variety of ways, for example, by utilizing a different material, by treating the material e.g., by utilizing stainless steel annealing to impart selective degrees of hardness to the different portions of the stent. Alternatively, if, e.g., NiTi (Nitinol) is utilized, selected portions of the stent may be selectively thermo-mechanically treated so that portions of the stent, e.g., the U-shaped members, will remain in a martensitic phase while other portions of the stent will be transformed into austenitic phase in this section to yield different properties. Greater flexibility may also be achieved by changing the shape of the "U", for example to a "Z" or an "S" (as shown in FIG. **11**), or by reducing the amount of material utilized to make the U-shaped loops **8'** and **9'**. In the embodiment shown in FIGS. **1** and **2**, the U-shaped loops **8'** and **9'** of row **25** are provided with the same thickness of material as the U-shaped loops **8** and **9** of the cells **3** in rows **26**, **27**, and **28**, however, U-shaped loops **8'** and **9'** are not as wide. As shown in FIGS. **1** and **2**, U-shaped loops **8'** and **9'**

have a width W1 that is less than the width W2 of U-shaped loops **8** and **9** in the cells **3** of rows **26**, **27**, and **28**. In a preferred embodiment, W1 is about 50% narrower than W2. In an especially preferred embodiment, W1 is about 40% narrower than W2.

FIG. **3** is a side-by-side comparison of two stent sections and shows a conventional stent **12** compared to the stent **1**, shown in FIGS. **1** and **2**. FIG. **4** shows stents **1** and **12** shown in FIG. **3** as they appear when they are crimped on a balloon and bent as they would be during insertion around a curve in a vessel. As shown in FIG. **4**, conventional stent **12** flares at its leading edge **13** in contrast to stent **1** which does not. FIG. **5** shows the stents of FIG. **4** after the stents have been expanded in a curve. The tip of conventional stent **12** produces a protrusion or sharp point **13** which could cause local pressure and possible trauma to the vessel wall. In contrast, the stent **1** constructed in accordance with the invention bends gently at its end **2** without forming a protrusion or sharp point because the deformation of the of U-shaped loops **8'** and **9'** in distal row **25** make the end **2** softer.

FIG. **6** shows the stents **1** and **12** of FIG. **3** at partial expansion (before reaching maximum pressure) disposed on a substantially straight catheter. As shown, although the two stents **1** and **12** are subjected to the same outward force, the end **2** of stent **1** is less expanded than the end **13** of conventional stent **12** demonstrating the increased radial force of the end **2** of stent **1** constructed in accordance with the invention. At full pressure the radii of the stents **1** and **12** will be equal, however, the end **2** of stent **1** will have greater radial resistance to collapse than the end **13** of stent **12**.

FIG. **7** shows an alternative embodiment of the invention. As shown in FIG. **7**, the cells **3'** in row **25** are provided with a first member **4'** and third member **6'** that are shorter than second member **5'** and fourth member **7'**. The cells **3'** in row **25** are provided with a first U-shaped loop **8'** and a second U-shaped loop **9'** that are thinner than the U-shaped loops **8** and **9** in the cells **3** in rows **27** and **28**. The cells **3"** in row **26** are provided with first U-shaped loops **8"** and second U-shaped loops **9"** that are narrower than the U-shaped loops **8** and **9** in the cells **3** in rows **27** and **28**.

FIG. **8** shows the stent **20** of FIG. **7** during partial expansion of the stent showing the decreased expansion of row **25** at partial expansion because of the higher radial force of the end **2** of the stent which results from construction with shorter C-shaped loops **10'** in row **25**, construction with narrower, i.e., more flexible, U-shaped loops **8'** and **9'** in row **25**, and **8"** and **9"** in row **26**.

FIG. **9** shows the stent **20** of FIGS. **7** and **8** after it has been expanded in a curved vessel and shows the bends of the U-shaped loops **8'** and **9'** in row **25** and **8"** and **9"** in row **26** which allows the end portion **2** of the stent **20** to more readily conform to the curve of the vessel, creating smooth ends with no sharp points or projections projecting into the vessel wall.

The changes can be made on one side only or on both sides of the stent as specific applications dictate. Additionally, different combinations of embodiments of the invention may be mixed such as using thinner U-shaped loops, longer U-shaped loops or different shaped loops, e.g., "Z" or "S".

One example of how this may be achieved is shown in FIG. **10**. FIG. **10** shows how the stent shown in FIG. **7** may be modified, if additional flexibility is desired. As shown in FIG. **10**, the distal row **25**, and the proximal row **29** of stent **30** are provided with first and second U-shaped loops that are more flexible than the U-shaped loops in the other rows of the stent disposed between the distal and proximal rows **25** and **29**. In the embodiment of the invention shown in FIG. **10**, the distal row **25** is provided with shortened members **4'** and **6'** and more flexible U-shaped loops **8'** and **9'**, as previously discussed, and the proximal row **29** is provided with shortened second and fourth members **5"** and **7"** and more flexible U-shaped loops **8'"** and **9'"**. This arrangement imparts greater radial strength and greater flexibility to both ends of the stent.

If even greater flexibility at the ends of the stent is desired, the stent shown in FIG. **10** may be modified by replacing the U-shaped loops in rows **26** and **28** with more flexible loops. Thus, the distal row, the row proximal to the distal row, the proximal row, and the row distal to the proximal row are provided with U-shaped loops that are more flexible than the U-shaped loops in the cells in the remaining rows of the stent.

The present invention contemplates a number of different variations and changes in different properties to achieve other non uniform features such as, but not limited to, cell size, cell shape, radio-opacity, etc. on the above-described preferred embodiments. The specified changes are brought only as an example for the application of the general concept, which is the basis for the present invention that stents with varying mechanical properties between sections along the stent may correct undesired effects at singular points such as stent ends and provide for a better fit to a vessel with properties changing along its axis. It is to be understood that the above description is only of one preferred embodiment, and that the scope of the invention is to be measured by the claims as set forth below.

What is claimed is:

1. An expandable stent, comprising: a plurality of interconnected flexible cells defining a stent having a proximal end and a distal end and a longitudinal axis, the cells arranged in a plurality of interconnected flexible rows disposed along the longitudinal axis of the stent with a distal row disposed at the distal end of the stent and a proximal row disposed at the proximal end of the stent, wherein the cells disposed in the distal row of the stent are adapted to exert greater radial force and are adapted to be more flexible than the cells disposed in the rows disposed between the distal row and the proximal end of the stent, and, wherein the cells in the distal row are of a thinner gauge than the gauge of the material utilized in the cells disposed between the distal row and the proximal end of the stent.

2. An expandable stent, comprising: a plurality of interconnected flexible cells defining a stent having a proximal end and a distal end and a longitudinal axis, the cells arranged in a plurality of interconnected flexible rows disposed along the longitudinal axis of the stent with a distal row disposed at the distal end of the stent and a proximal row disposed at the proximal end of the stent, wherein the cells disposed in the distal row of the stent are adapted to exert greater radial force and are adapted to be more flexible than the cells disposed in the rows disposed between the distal row and the proximal end of the stent, and, wherein the cells in the distal row are made of a material that is more flexible than the material utilized in the cells disposed between the distal row and the proximal end of the stent.

3. An expandable stent, comprising: a plurality of interconnected flexible cells defining a stent having a proximal end and a distal end and a longitudinal axis, the cells arranged in a plurality of interconnected flexible rows disposed along the longitudinal axis of the stent with a distal row disposed at the distal end of the stent and a proximal row

disposed at the proximal end of the stent, wherein the cells in the distal row of the stent and the cells disposed in the proximal row of the stent are adapted to exert greater radial force and are adapted to be more flexible than the cells disposed in the rows disposed between the distal row and the proximal row, and, wherein the cells in the distal row and the proximal row are of a thinner gauge than the gauge of the material utilized in the cells disposed between the distal row and the proximal row of the stent.

4. An expandable stent, comprising: a plurality of interconnected flexible cells defining a stent having a proximal end and a distal end and a longitudinal axis, the cells arranged in a plurality of interconnected flexible rows disposed along the longitudinal axis of the stent with a distal row disposed at the distal end of the stent and a proximal row disposed at the proximal end of the stent, wherein the cells in the distal row of the stent and the cells disposed in the proximal row of the stent are adapted to exert greater radial force and are adapted to be more flexible than the cells disposed in the rows disposed between the distal row and the proximal row, and, wherein the cells in the distal row and the proximal row are made of a material that is more flexible than the material utilized in the cells disposed between the distal row and the proximal row of the stent.

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